UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA *et al.*, *ex rel.* TRICIA NOWAK and ENDA DODD,	)	
Plaintiffs,	)	
v.	)	CIVIL ACTION NOS. 1:08-cv-10368 & 1:09-cv-11625
MEDTRONIC, INC.,	)	
Defendant.	)	

MEMORANDUM AND ORDER
July 27, 2011

Relators Tricia Nowak and Enda Dodd (the "relators") bring this *qui tam* action against Medtronic, Inc., on behalf of the United States, twenty-two states, and the District of Columbia. The relators allege that Medtronic knowingly and intentionally made false statements and caused to be submitted false claims in violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729(a), and similar state statutes and that it wrongfully terminated Nowak in violation of the anti-retaliation provision of the FCA, 31 U.S.C. § 3730(h) and related California laws. Medtronic has moved to dismiss the relators' claims. I will grant in part and deny in part Medtronic's motion to dismiss.

I. STATUTORY FRAMEWORK

A. False Claims Act

The False Claims Act, 31 U.S.C. § 3729 *et seq.*, permits an individual, or relator, to file a *qui tam* action on behalf of the United States against persons or entities who knowingly submit or

cause to be submitted false claims to the government or who knowingly make, use, or cause to be made false records or statements to get a false claim paid by the government. 31 U.S.C. § 3729(a)(1); 31 U.S.C. § 3730(a)(2).[1] Complaints filed in *qui tam* actions are filed under seal and first served upon the

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[1]On May 20, 2009, the False Claims Act was amended by the Fraud Enforcement & Recovery Act ("FERA"), Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621 (2009). The relevant provision now states that

> any person who--
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . .
> is liable to the United States Government for a civil penalty . . . .

31 U.S.C. § 3729(a)(1). The parties dispute whether FERA applies to the instant action.

FERA provides that amendments to the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, take effect upon enactment except for the amendment to the old § 3729(a)(2), which "shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act . . . that are pending on or after that date." FERA § 4(f)(1), 123 Stat. at 1625. Courts initially disagreed as to whether "claims" refers to actions brought under the FCA or the underlying fraudulent claims submitted to the government. *Compare Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1327 n.3 (11th Cir. 2009) (interpreting "claim" "to mean 'any request or demand . . . for money or property,' as defined by 31 U.S.C. § 3729(b)(2)(A) (as amended May 2009)"), *with United States ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94, 113 (2d Cir. 2010) (interpreting "claim" to be the cause of action). In the meantime, courts have "almost uniformly interpreted 'claims' to mean claims for reimbursement." *United States ex rel. Carpenter v. Abbott Labs., Inc.*, 723 F. Supp. 2d 395, 402 (D. Mass. 2010) (collecting cases). I see no reason to depart from the majority view and likewise will apply § 3729(a)(2) in its pre-amendment form to all claims for reimbursement no longer pending as of June 7, 2008, and will apply the amended version to those claims pending on or after June 7, 2008.

government, which has sixty days to decide whether to intervene and assume primary responsibility over the action. 31 U.S.C. § 3730(b)(2), (b)(4), (c). The complaint may be unsealed and served on the defendant only at the court's direction. 31 U.S.C. § 3730(b)(2). The relator is eligible to collect as much as thirty percent of any damages awarded in such an action regardless of whether the government intervenes. 31 U.S.C. § 3730(d).[2]

The FCA also provides whistleblower protection to employees who take action to prevent FCA violations. 31 U.S.C. § 3730(h).[3] An employee terminated because she attempts to stop a violation of the False Claims Act is entitled to reinstatement, back pay, and other appropriate compensation. 31 U.S.C. § 3730(h)(2).

The considerable financial incentive to bringing a False Claims Act action both "encourages would-be relators to expose fraud" and "serves to attract those looking to capitalize on

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[2]Many states — and the District of Columbia — have similar false-claims or Medicaid-fraud acts that operate in the same manner as the federal FCA statute. *See, e.g.*, Indiana False Claims & Whistleblower Protection Act, Ind. Code Ann. § 5-11-5.5-1 *et seq.*; Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053 *et seq.*; District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. § 2-308.13 *et seq.* A number of states have submitted statements of interest in this action.

[3]FERA also amended 31 U.S.C. § 3730(h). Because Nowak's termination took place after May 20, 2009, the amended version of that provision will govern this case as to that claim while the pre-amendment version will apply to any retaliatory actions that Nowak alleges occurred prior to that date. *See* FERA § 4(f), 123 Stat. at 1625.

fraud already exposed by others." *United States ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 107 (1st Cir. 2010). Consequently, there are several statutory limitations to filing *qui tam* actions under the FCA. Once a relator files a *qui tam* action against a defendant, "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). In addition to this "first-to-file" bar, no person may bring a False Claims Act action against a defendant based on prior public disclosures of the alleged fraud "in a criminal, civil, or administrative hearing, in a congressional, administrative or Government Accounting Office report, hearing, audit, or investigation, or from the news media."[4] 31 U.S.C. § 3730(e)(4)(A). When this public disclosure bar applies, only the Attorney General or an "original source of the information" may bring such an action. 31 U.S.C. § 3730(e)(4)(A). A relator

[4]On March 23, 2010, Congress amended the public disclosure bar by enacting the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. 111-148, 124 Stat. 119. The amended provision reads: "The court shall dismiss an action or claim under this section, unless opposed by the Government, if *substantially the same allegations or transactions* as alleged in the action or claim were publicly disclosed . . ." in the listed sources. 31 U.S.C. § 3730(e)(4) (emphasis added). The Supreme Court has held that this provision is not retroactive and, therefore, I will apply § 3730(e)(4) as it was at the time that the complaints were filed, that is, prior to PPACA. *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 130 S. Ct. 1396, 1400 n.1 (2010); *see also United States ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 107 n.2 (1st Cir. 2010).

claiming to be an "original source" must (1) "ha[ve] 'direct and independent knowledge' of the information supporting her claims and (2) [must have] 'provided the information to the Government before filing an action.'" *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 16 (1st Cir. 2009), *cert. denied*, 130 S. Ct. 3454 (2010) (quoting 31 U.S.C. § 3730(3)(4)(B)).

B. Federal Regulation of Medical Devices

The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, regulates the approval and marketing of medical devices. No medical device may be marketed in the United States without prior approval by the Food and Drug Administration ("FDA") for its intended use. 21 U.S.C. § 360.

The FDCA creates three categories of devices that are subject to increasing levels of regulatory oversight: Class I (low risk, general controls), Class II (medium-risk, special controls), and Class III (high-risk, premarket approval). 21 U.S.C. § 360c(a)(1). Class III devices include those for which it is impossible to establish special regulations that assure safety, those "purported or represented to be for use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," and those that "present[] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C).

In order to market a Class III device, a manufacturer must submit a comprehensive application to the FDA for premarket approval. 21 U.S.C. § 360e(c). The device is approved only for its "intended uses" or "the objective intent of the persons legally responsible for the labeling of the devices." 21 C.F.R. § 801.4. The FDA must also approve any changes to the intended uses of a Class III device. 21 C.F.R. §§ 801.4, 807.81.

There are two ways in which to avoid the costly and time-consuming premarket-approval process: the investigational device exception, 21 C.F.R. § 812.1 *et seq.*, and "510(k)" clearance based upon prior approval of a substantially equivalent device, 21 U.S.C. § 360; 21 C.F.R. § 807.87(k).

To obtain 510(k) clearance to market a device, the manufacturer must submit a premarket notification, including a certified "statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted." 21 C.F.R. § 807.87(k). The notification must include the intended uses of the device, the conditions the device is designed to treat, and the relevant patient population. 21 C.F.R. § 807.92(a)(5).

Clearance through the 510(k) process does not constitute FDA "approval" of the device; it limits the cleared use of the device to those indications listed in the application as the intended

uses. 21 U.S.C. § 352(f); 21 C.F.R. § 801.5; 21 C.F.R. § 807.97. These limited indications must be listed on the label, and a manufacturer may only promote a device for cleared or approved indications. 21 U.S.C. § 352(f); 21 C.F.R. § 807.81(a)(3).

Any promotion of a device for any indication not approved or cleared by the FDA and indicated on the label is considered an "off-label" promotion and is unlawful. *See* 21 U.S.C. § 331(d). However, off-label use of devices by physicians is not *per se* unlawful. *See Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 350 (2001) (recognizing that "'off-label' usage of medical devices . . . is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine" (citations omitted)). Courts have also recognized that "off-label use of a drug or medical device is not the same as a medically unnecessary use of that drug or device." *United States ex rel. Bennett v. Medtronic, Inc.* ("*Bennett I*"), 747 F. Supp. 2d 745, 751 (S.D. Tex. 2010) (collecting cases); *see also Svidler v. U.S. Dep't of Health & Human Servs.*, No. C 03-3593, 2004 WL 2005781, at *5 (N.D. Cal. Sept. 8, 2004) ("[T]he FDA can restrict a company from marketing off-label uses, but cannot prevent a doctor from prescribing a device for an off-label use for any purpose she deems medically necessary." (citing *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998))).

C. Federal Reimbursement for Medical Devices

Medicare is the federally subsidized health insurance program for the elderly and disabled established under the Social Security Act ("Medicare Act"), 42 U.S.C. § 1395 *et seq.* Whereas Medicare coverage for off-label uses of pharmaceuticals is highly restricted, "Medicare reimbursements for off-label uses of medical *devices* are not addressed within the Medicare Act itself." *Bennett I*, 747 F. Supp. 2d at 752 (citing *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 73 (2d Cir. 2006)). The Medicare Act provides only "[b]road wording," *Yale-New Haven Hosp.*, 470 F.3d at 73, excluding "any expenses incurred for items or services [which] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member," 42 U.S.C. § 1395y(a)(1)(A). The Secretary for the Department of Health and Human Services ("DHHS") has "wide discretion" in "specifying those services that are covered under the 'reasonable and necessary' standard." *Yale-New Haven Hosp.*, 470 F.3d at 74 (citing 42 U.S.C. § 1395ff(a)).

Before 1995, the DHHS manuals prohibited Medicare reimbursement "for devices not approved by the FDA for commercial distribution because they were not considered 'reasonable and necessary' under 42 U.S.C. § 1395y(a)(1)." *See Bennett I*, 747 F. Supp. 2d at 752 (citations and internal quotation marks omitted);

see also In re Cardiac Devices Qui Tam Litig., 221 F.R.D. 318, 329 (D. Conn. 2004) ("Between July 1986 and November 1995, payment by Medicare for any medical procedure in which a medical device was used was expressly predicated upon the FDA's approval of the medical device for marketing."). In 1995, the DHHS Secretary published superseding regulations "allowing Medicare coverage for Category B investigational devices under the 'reasonable and necessary' standard," but maintaining a categorical prohibition on off-label use of Category A investigational devices. *See Bennett I*, 747 F. Supp. 2d at 752 (quoting *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. at 325). Devices "believed to be in . . . Class II" — such as Medtronic's biliary stents at issue in this case — are Category B, "nonexperimental/investigational" devices, 42 C.F.R. § 405.201(b), which Medicare contractors "*may* approve . . . if all other coverage requirements are met," 42 C.F.R. § 405.211(b) (emphasis added). *See also Bennett I*, 747 F. Supp. 2d at 753. In considering whether to cover a particular Category B device, "Medicare contractors must consider whether any restrictions concerning site of service, *indications for use*, or any other list of conditions for coverage have been placed on the device's use." 42 C.F.R. § 405.211(c) (emphasis added).

TRICARE (formerly CHAMPUS[5]) and CHAMPVA are also federal healthcare programs. Administered by the Department of Defense, TRICARE is "a comprehensive managed health care program for the delivery and financing of health care services in the Military Health System" covering qualifying retired military personnel and military dependents and spouses. 32 C.F.R. §§ 199.17(a), 199.3. As of September 2010, TRICARE had 5.8 million enrolled users and 3.8 million non-enrolled users. *See* http://www.tricare.mil/mediacenter/press_facts.aspx.

Much like Medicare, TRICARE coverage for medical devices depends on the medical necessity of the procedure. TRICARE "will pay for *medically necessary services and supplies* required in the diagnosis and treatment of illness or injury." 32 C.F.R. § 199.4(a)(1)(I) (emphasis added). TRICARE coverage of off-label medical devices has also changed in the recent past, although in the case of TRICARE, the coverage has become more restrictive. The 2002 TRICARE Policy Manual, ch. 8, § 5.1, states that the "[u]se of FDA-approved devices for off-label or non-FDA approved applications may be covered if documented by reliable evidence as safe, effective, and in accordance with nationally accepted standards of practice in the medical community." The superseding

[5]In 1994, TRICARE replaced CHAMPUS as the health care program for active-duty military personnel, retirees, and their families. *See* http://www.tricare.mil/faqs/question.aspx?ID=34&page=0&search=champus&click=ibGo.X.

2007 TRICARE Policy Manual, ch. 8, § 5.1(III)(B), however, excludes "off-label uses of devices."[6]

CHAMPVA is administered by the Department of Veterans Affairs ("VA") and provides health care to qualified veterans of the U.S. Armed Forces. *See* http://www.va.gov/hac/forbeneficiaries/champva/champva.asp. CHAMPVA coverage of off-label medical devices is similar to the 2002 TRICARE Policy Manual's coverage; under chapter 2, § 17.2(III)(C), of the 2005 CHAMPVA Policy Manual, "use of FDA-approved devices for off-label or non-approved FDA applications may be covered if documented by reliable evidence as safe, effective, and in accordance with nationally accepted standards of practice in the medical community."

II. FACTUAL AND PROCEDURAL BACKGROUND

As I must, when considering a motion to dismiss, I recount the facts as alleged in the complaint as true:

A. The Parties

Medtronic is one of the world's largest medical technology companies and employs approximately 38,000 people worldwide. (Consol. Compl. ¶ 3.) A Fortune 200 company, Medtronic saw

[6]The Department of Defense has since issued a notice of proposed rulemaking clarifying that the exclusion of "unproven" devices is *not* to include off-label use of devices in certain circumstances. This rulemaking would make TRICARE coverage consistent with TRICARE's coverage of off-label drug use. However, the rule has not yet been amended.

nearly $15 billion in revenue for fiscal year 2009. (Consol. Compl. ¶ 3.)

Both relators, Tricia Nowak and Enda Dodd, are former employees of Medtronic. (Consol. Compl. ¶¶ 11–12.) Nowak was a sales representative in Medtronic's EndoVascular sales group from May 2005 until her termination on August 7, 2009. (Consol. Compl. ¶ 11.) In 1987, Dodd began working as a senior engineer for a medical device company in Ireland. (Consol. Compl. ¶ 12.) Medtronic eventually acquired Dodd's company in 1999, and, in 2003, Dodd moved to California to be a senior research manager tasked with overseeing the development of peripheral vascular products for Medtronic, including Medtronic's line of biliary stents. (Consol. Compl. ¶ 12.) Medtronic terminated Dodd in 2008, at which time Dodd and Medtronic entered into a termination agreement that included a release of legal claims. (Nemirow Decl., Ex. S.)

B. Medtronic's Line of Biliary Stents

Medtronic develops and produces a line of biliary stents, including the Bridge, Aurora, Assurant, Racer, and Complete SE stent lines. (Consol. Compl. ¶¶ 69, 72, 74.) A stent is a tubular device that can be implanted in tubular structures of the body such as blood vessels (vascular stents) and bile ducts (biliary stents) and is used to relieve or prevent blockages. (Consol. Compl. ¶ 31.) A biliary stent is defined by federal law

as a "tubular flexible device used for temporary or prolonged drainage of the biliary tract, for splinting of the bile duct during healing, and for preventing stricture of the bile duct." 21 C.F.R. § 876.5010(a). Biliary stents are generally used to relieve the pain caused by bile blockages experienced by a limited number of late-stage cancer patients. (Consol. Compl. ¶ 33.) As such, their intended use is palliative and short-term. (Consol. Compl. ¶¶ 33, 58.)

Biliary stents are considered medium-risk, Class II devices and are classified under federal law as gastro-enterological. (Consol. Compl. ¶¶ 33, 60.) *See* 21 C.F.R. § 876.5010(b). Medtronic's biliary stents were cleared by the FDA for entry into the market through the less-costly and less-comprehensive 510(k) process. (Consol. Compl. ¶ 60.) Because the biliary stents are short-term and not life-sustaining, less rigorous clinical studies are considered sufficient to assure their safety for their intended use in the biliary tree only. (Consol. Compl. ¶ 33.)

C. Vascular Stents

In contrast to biliary stents, the FDA considers stents used in the vascular system to be high-risk devices subject to regulation as Class III devices. (Consol. Compl. ¶ 34.) The vascular system consists of the body's blood vessels, and the peripheral vascular system (or "periphery") includes the renal,

iliac, and superficial femoral arteries – all blood vessels not located within or near the heart. (Consol. Compl. ¶¶ 34, 93.) Stents are used in the peripheral vasculature to treat vascular disease by relieving blockages in the blood vessels; as such, their use is not palliative. (Consol. Compl. ¶ 34.) Peripheral vascular stents are implanted for permanent use and undergo far longer-term and variable stresses than biliary stents due to their location in the body. (Consol. Compl. ¶ 34.) As Class III devices, vascular stents require premarket approval, including clinical tests and institutional board review. (Consol. Compl. ¶¶ 34, 36.)

D. Stent Markets

There are vastly different potential markets for biliary and vascular stents. Biliary stents are generally intended for use in treating those with pancreatic and bile-duct cancer, a population estimated at slightly more than 40,000 in 2007. (Consol. Compl. ¶ 35.) By contrast, the number of Americans suffering from peripheral vascular disease numbers in the millions. (Consol. Compl. ¶ 35.) Nevertheless, there are very few stents approved for use in the peripheral vasculature, whereas there are dozens of biliary-stent models with annual sales totaling billions of dollars. (Nemirow Decl., Ex. O.) *The New York Times* has estimated that off-label uses of biliary stents constitute ninety percent of the biliary-stent market, and

other estimates put the ratio of on- to off-label uses at 1:250. (Nemirow Decl., Ex. O; Consol. Compl. ¶ 92.) Barnaby Feder, *Little Data on Stent's Most Common Use*, N.Y. Times, Jan. 21, 2008, at C2. Not surprisingly, as a result, off-label use of biliary stents for treating peripheral vascular disease has become commonplace. By 2001, cardiologists and other physicians were discussing the difficulty of conducting clinical trials for peripheral stents because of the "rampant off-label use of [biliary] stents." (Nemirow Decl., Ex. I, Tr. at 204.) An industry journal declared, in 2001, that "[p]eripheral stenting . . . is already regarded as the standard of care, even though the procedure is off-label." (Nemirow Decl., Ex. J.)

The relators allege facts suggesting that there is some doubt regarding the safety and effectiveness of off-label use of biliary stents in the vascular periphery. During the research and development of both the Racer and Complete SE biliary stents, Dodd voiced concerns to his supervisors that the biliary stents would crack or malfunction when used in the vasculature, where increased pulsation of the veins puts more stress on the stents. (Consol. Compl. ¶¶ 66, 126.) The FDA reported that, as off-label use of biliary stents has increased, the number of adverse events involving those devices has increased substantially. (Consol. Compl. ¶ 128.) In 2008, an article in the *American Journal of Therapeutics* reported that there is little "clinical data" to

support "clinical effectiveness and safety" of biliary stents used in the periphery and that eighty-one percent of malfunctions and more than eighty-seven percent of adverse events involving biliary stents occurred when the biliary stents were used off-label in the vascular system. (Consol. Compl. ¶ 137 (quoting Jonathan Bridges & William H. Maisel, *Malfunctions and Adverse Effects Associated with Off-Label Use of Biliary Stents in the Peripheral Vasculature*, 15 Am. J. Therapeutics 1 (2008)).) These adverse events can lead to a "need for surgery to retrieve retained device materials, or to repair a ruptured vessel, to serious vascular injury (vessel perforation, dissection, and thrombosis), stroke, heart attack, and death." (Consol. Compl. ¶ 138.)

E. FDA Regulation of Stent Marketing

In response to the increased use of off-label biliary stents and reporting of adverse complications from that use, the FDA increased its vigilance and regulation of biliary-stent sales and promotion. (Consol. Compl. ¶ 37; Nemirow Decl., Ex. K at 1.) In 1999, for example, the FDA required biliary stents to carry a contraindication stating that biliary stents are not approved or tested for use in the vascular system. (Consol. Compl. ¶ 37.) The FDA reminded biliary-stent manufacturers of these additional labeling requirements again in 2003. (Nemirow Decl., Ex. K at 2.) In 2004, the FDA issued a recall of a biliary stent product

manufactured by Cordis because the FDA had not approved the instructions. (Nemirow Decl., Ex. K at 2.) The FDA also recalled Medtronic's Assurant system in 2003 because of dangers arising from its use in the vasculature. (Consol. Compl. ¶ 126.)

In March 2007, the FDA took the unusual step of calling a meeting of biliary-stent manufacturers to convey the government's concerns regarding off-label use and promotion of biliary stents in the peripheral vascular system. (Consol. Compl. ¶ 38; Nemirow Decl., Ex. K at 1.) This meeting was reported by industry and national media outlets. (Nemirow Decl., Exs. K, M, O, P.) Medtronic representatives attended the March 2007 meeting, at which the FDA announced that, as of that time, it was foregoing compliance action relating to the off-label use and promotion of biliary stents in the hope that the manufacturers would come into self-compliance. (Consol. Compl. ¶ 38)

F. Relators' Allegations of Fraud by Medtronic

The Consolidated Complaint appears to outline two interrelated allegations of fraud under the FCA. Although the relators do not clearly define these two allegations, the Consolidated Complaint can be read to describe a fraudulent scheme of "false certification" and a fraudulent scheme of "off-label promotion." (*See* Consol. Compl. ¶¶ 5–9.)

First, the relators allege that Medtronic knowingly submitted false certifications to the FDA, in order to obtain

510(k) clearance, of their stents as biliary stents despite the fact that the stents were designed, intended, and promoted as vascular stents. (Consol. Compl. ¶ 140.) Therefore, the relators contend, *any* claim for reimbursement submitted to the government for use of those stents was fraudulent – whether on- or off-label – because it necessarily would have been based on a fraudulent clearance. (Consol. Compl. ¶ 174.)

Second, the relators allege that Medtronic knowingly promoted off-label use of its biliary stents in the vascular system, thereby causing third parties to submit fraudulent claims for reimbursement to the government for unlawful and nonreimbursable off-label uses. (Consol. Compl. ¶¶ 140, 174.)

1. False Certification Scheme

The relators allege that, although Medtronic cleared its biliary stents through the 510(k) process as Class II devices, the defendant designed the devices as vascular stents and intended to market them exclusively as such. (Consol. Compl. ¶ 57.) Because the 510(k) process requires certification that the device is intended for its indicated use and is "substantially similar" to prior devices, Medtronic allegedly made false statements to FDA by mischaracterizing the vascular stents as biliary stents. (Consol. Compl. ¶ 62.)

The relators recount the design and approval process for two of Medtronic's biliary stents: the Racer and the Complete SE.

Dodd, a senior research manager, was brought in to finalize the Racer stent for its market release. (Consol. Compl. ¶ 64.) He worked on problems surrounding the integrity of the stent when used in renal arteries. (Consol. Compl. ¶ 64.) Although the design process followed guidelines for biliary stents, "the sole and only commercial intent, as articulated by [other senior project managers], was the treatment of stenosed (blocked) renal (kidney) arteries, a blood contact vascular indication." (Consol. Compl. ¶ 65.) The Racer Integrated Business Plan also "set out the business–directed process of a non-vascular FDA cleared indication while promoting the new product offering exclusively for the treatment of renal artery disease." (Consol. Compl. ¶ 67.) The target physician–audience was cardiologists. (Consol. Compl. ¶ 67.)

Surprised by this promotion strategy, Dodd reviewed the records on the development of previous biliary stents and found a similar pattern in the approval processes of the Bridge, Aurora, and Assurant stents. (Consol. Compl. ¶¶ 68–69.) Dodd expressed his concerns to his supervisors but was warned not to delay Racer's market release. (Consol. Compl. ¶ 71.) The FDA cleared Racer in November 2003 for a biliary indication only. (Consol. Compl. ¶ 72.) Medtronic product launch materials, however, announced that "Racer is Medtronic Vascular's fourth entry into the renal stenting segment" and is "forecasted to generate $4.25M

in revenue for FY04 and $13.44M for FY05." (Consol. Compl. ¶ 73.) The Racer replaced — and was promoted as replacing — a Medtronic stent that had obtained premarket approval as a peripheral vascular stent. (Consol. Compl. ¶ 73.)

The Consolidated Complaint outlines a similar development and clearance process for the Complete SE stent, which the FDA cleared for the market as a biliary stent in November 2007. (Consol. Compl. ¶ 74.) In late 2003, Dodd began working on the development of the Complete SE, which he was originally told would be submitted to the FDA for premarket approval as a peripheral stent as well as for clearance as a biliary stent. (Consol. Compl. ¶ 75.) By summer 2005, however, Dodd's supervisor informed Dodd that no such premarket approval would be sought, and "[t]he management team developed Product Launch Plans for the launch of COMPLETE SE that were predicated entirely upon revenue forecasts from off-label sales." (Consol. Compl. ¶ 78.) In advance of the 2006 Vascular Interventional Advances Conference, at which Medtronic promoted off-label use of the Complete SE, Medtronic's chief executive officer, William Hawkins, congratulated Dodd's superiors for eliminating resistance to clearing the Complete SE via the 510(k) process. (Consol. Compl. ¶ 82.) Ultimately, Medtronic pursued — and obtained — 510(k) clearance despite concerns raised by its own regulatory director. (Consol. Compl. ¶ 84.)

2. Off-Label Promotion Scheme

The relators outline in great detail various means by which Medtronic promoted off-label use of its biliary stents. In addition to promoting off-label uses to cardiologists and other physicians at industry conferences and advisory training sessions at its research facility, the Consolidated Complaint alleges that Medtronic sent engineers and project managers to clinical sites to observe implantation of biliary stents in the vascular system. (Consol. Compl. ¶ 86.) Promotional materials and annual revenue projections routinely characterized biliary stents as peripheral products. In 2005, annual financial operating plans projected millions of dollars in off-label sales, and promotional materials entitled "Medtronic Peripheral Solutions" described each biliary stent, including the yet-to-be marketed Complete SE. (Consol. Compl. ¶ 104.) An early Racer brochure announced Racer as "the first cobalt chromium stent launched for peripheral applications," and a Peripheral Product Catalog included biliary stents. (Consol. Compl. ¶ 106.) Medtronic does not promote the use of the biliary stents to gastroenterologists or for their intended use in the biliary tree. (Consol. Compl. ¶¶ 101, 105.)

Medtronic instructed its salespeople to promote off-label use directly to hospitals and other health professionals. Medtronic originally promoted use of biliary stents in the peripheral vasculature through its Peripheral Products Group.

(Consol. Compl. ¶ 93.) However, after the FDA's March 2007 industry-wide meeting, Medtronic dissolved this sales group. (Consol. Compl. ¶ 93.) Off-label promotion of biliary stents was then absorbed into a new Cardio Vascular Division ("Vascular Division"). (Consol. Compl. ¶ 94.) The Vascular Division includes two groups: the Endovascular Group, which primarily promotes the AnueRx AAAdvantage Stent Graft System ("AneuRx") and the Talent Abdominal Stent Graft to combat abdominal aortic aneurysms; and the Coronary Group, which promotes a variety of coronary stents, catheters, and guidewires. (Consol. Compl. ¶¶ 96–97.)

Medtronic required sales representatives in the Endovascular and Coronary Groups, as part of their duties, to sell "peripheral products," of which biliary stents — for use in the vasculature — are the primary, if not only, products. (Consol. Compl. ¶ 99.) Sales representatives' compensation packages also depended on peripheral sales, including peripheral commissions, peripheral bonuses, and an incentive "Summit Quest Contest" that included a peripheral quota for eligibility. (Consol. Compl. ¶¶ 109–10, 121.) Medtronic also kept track of peripheral sales, distributed rankings of top sellers of peripheral products, and pressured Nowak to sell peripheral products even though she refused to sell for off-label use. (Consol. Compl. ¶¶ 109, 111–15.) Quarterly sales reports listed the number of peripheral

devices sold by each sales representative, as well as the details of each sale (product number, buyer, price, date). (Consol. Compl. ¶¶ 115–16.)

Nowak received pressuring emails when she refused to sell the biliary stents off label. (Consol. Compl. ¶¶ 116–19.) In one 2008 quarterly evaluation, Nowak's high sales were praised, but the evaluation noted that her "peripheral business was non existent [*sic*]. There is an expectation to sell the peripheral portfolio and that will be an area of focus in FY09." (Consol. Compl. ¶ 118.) A November 2008 email stated that "[t]he expectation is 10K [of peripheral sales] per rep per qtr" and listed available products as "a selection of Biliary stents: Racer, Assurant and Complete SE." (Consol. Compl. ¶ 120.)

Medtronic also encouraged sales representatives to attend vascular procedure trainings explaining "common peripheral interventions, *i.e.*, renal, iliac, SFA" and "what size devices to use along with ancillary equipment selection." (Consol. Compl. ¶ 123.) A September 11, 2007, email from a regional sales manager characterized these trainings as a "great opportunity for YOU, yes YOU, to get some hands on peripheral training" to "enhance your ability to talk with your customers about the details of this type of procedure." (Consol. Compl. ¶ 123.)

Medtronic was aware of FDA scrutiny and took steps to conceal its off-label promotional activities. At the same time

Medtronic was rearranging its sales force in light of FDA's March 2007 meeting, it instructed sales representatives to "destroy" promotional materials listing biliary stents as "peripheral devices." (Consol. Compl. ¶ 106.) In September 2007, an email sent to the entire U.S. sales force warned that, "[a]s you know, the industry's sales practices of [sic] biliary stents have been under intense scrutiny by the FDA." (Consol. Compl. ¶ 134.) The email included an attachment outlining "Do's and Don'ts" that instructed sales representatives how to promote off-label use subtly. (Consol. Compl. ¶ 134.)

G. Nowak's Termination by Medtronic

Nowak had joined Medtronic's sales force in 2005 after seven years in the medical sales industry. (Consol. Compl. ¶ 141.) As a member of the Endovascular Group, Nowak primarily sold the AnueRx system. (Consol. Compl. ¶ 142.) She consistently exceeded her targets, was ranked among the top sales representatives in the country, and routinely received praise from her superiors. (Consol. Compl. ¶¶ 146, 153–55, 158.) However, she disagreed with the requirement — after the Peripheral Sales Group was dissolved — that she sell peripheral products off-label. (Consol. Compl. ¶¶ 147–48.)

On March 7, 2007, Nowak emailed her sales manager after attending legal training and viewing a DVD presentation that warned that off-label promotion was unlawful, that sales

representatives could be held personally responsible for off-label promotion, and that there was "no 'Nuremberg defense.'" (Consol. Compl. ¶¶ 125, 149–50.) Nowak expressed concern and asked how the Endovascular Group could be asked to sell peripheral products off-label given the legal restrictions and potential personal liability for sales representatives. (Consol. Compl. ¶¶ 125, 149–50.) Her sales manager did not reply to her email in writing, but orally told her that selling peripheral products was part of the job. (Consol. Compl. ¶¶ 125, 149–50.) Nowak was also asked to participate in a teleconference with independent and in-house legal counsel. (Consol. Compl. ¶ 150.) After the meeting, Nowak continued to excel, ranking eleventh and thirteenth in the country in successive quarters. (Consol. Compl. ¶ 154.) However, her continued refusal to sell biliary stents off-label attracted attention and pressure from her superiors and teasing by her colleagues. (Consol. Compl. ¶¶ 156–57.)

On March 5, 2008, Nowak filed a False Claims Act action against Medtronic, and, on April 17, 2008, she filed an amended complaint. (Consol. Compl. ¶ 157.) On June 5, 2008, Nowak again received praise for her continued excellent sales performance. (Consol. Compl. ¶ 158.) On July 2, 2008, Medtronic circulated a document-preservation notice and made public the FDA's investigation into Medtronic's off-label promotion practices.

(Consol. Compl. ¶ 159.) At this point, Nowak alleges, Medtronic began to establish a pretext for terminating her.

Despite ranking second highest in her region at the end of October 2008, Nowak was told by Medtronic on February 6, 2009, that she would be placed "on probation" and put on a Performance Improvement Plan that required her to achieve certain deliberately unachievable targets or risk termination. (Consol. Compl. ¶¶ 161, 163.) After receiving the plan for signature on March 11, 2009, half way into the fourth quarter, Nowak protested the implementation of the plan to a superior, who assured her that Medtronic would not terminate a "'top performer' who 'never missed an annual number since being at Medtronic.'" (Consol. Compl. ¶ 165.) Medtronic nevertheless placed Nowak on a second Performance Improvement Plan on May 8, 2009, and split her most lucrative territory with a sales representative who had been praised for his off-label promotion of biliary stents. (Consol. Compl. ¶ 166.) On August 4, 2009, the sales team was notified that overall revenue had fallen during the last quarter and that most sales representatives had not met their targets. (Consol. Compl. ¶ 169.) Nowak was terminated on August 7, 2009, and was told that her termination was due to a "lack of intensity." (Consol. Compl. ¶ 170.) She refused to sign a severance agreement or agree to voluntary termination. (Consol. Compl. ¶ 170.)

H. Procedural History

Nowak had filed her original complaint – under seal – against Medtronic in this court on March 5, 2008. (Consol. Compl. ¶ 157.) She filed an amended complaint – also under seal – on April 17, 2008. (Nowak Compl. (Doc. No. 7).) Dodd filed a similar complaint against Medtronic under the FCA in the United States District Court for the Northern District of California in April 2009. On September 28, 2009, that case was removed to this court and consolidated with Nowak's action. The United States chose not to intervene at the time but has, along with the states of Florida and Texas, submitted statements of interest in response to Medtronic's motion to dismiss this action for failure to state a claim. The two relators reached a relator-share agreement and, on February 19, 2010, filed a Consolidated Complaint against Medtronic on behalf of themselves, the United States, twenty-two states, and the District of Columbia.

In the Consolidated Complaint, Nowak and Dodd allege twenty-seven counts against Medtronic. (Consol. Compl. at 63–90.) Count I asserts a claim for treble damages and penalties under the FCA. The relators claim that Medtronic "knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval, and made, used and caused to be made and used false records and statements material to false claims" for each claim for reimbursement for a

biliary stent fraudulently approved by the FDA based on false statements and certifications and for each claim for reimbursement for a biliary stent promoted off-label and used in an unapproved manner. (Consol. Compl. ¶¶ 172–74.) The relators also alleged similar claims under the analogous false-claims statutes of twenty-two states and of the District of Columbia.[7]

Nowak also brought separate claims — under the federal False Claims Act, 31 U.S.C. § 3730(h), the California False Claims Act, Cal. Gov't Code § 12653(B), and California common law — alleging

[7] *See* Cal. Gov't Code § 12651(a)(1)–(2); D.C. Code Ann. § 2-308.14(a)(1)–(2); Fla. Stat. § 68.082(2)(a)–(b); Ga. Code Ann. § 49-4-168.1; Haw. Rev. Stat. § 661–21(a)(1)-(2); 740 Ill. Comp. Stat. § 175/3(a)(1)–(2); Ind. Code § 5-11-5.5-2(b)(1) and (8); Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:437.1 *et seq.*; Mass. Gen. Laws ch. 12 § 5B(1)–(2); Medicaid False Claim Act, Mich. Comp. Laws § 400.601 *et seq.*; Mont. Code Ann. § 17-8-403(1)(a)–(b); Nev. Rev. Stat. § 357.040(1)(a)–(b); N.J. Stat. Ann. § 2a:32c-3(a)–(b); N.M. Stat. § 27-14-4(A)–(C); N.Y. State Fin. Law § 189(1)(a)–(b); Okla. Stat. tit. 63, § 5053.1(B)(1)–(2); R.I. Gen. Laws § 9-1.1-3(a)(1)–(2); Tenn. Code Ann. § 71-5-182(a)(1)(A)–(B); Tex. Hum. Res. Code Ann. § 36.002(1) and (4); Va. Code Ann. § 8.01-216.3(a)(1)–(2); Wis. Stat. § 20.931(2)(a)–(b). (Consol. Compl. at 63–88.) The Consolidated Complaint raises a claim under the "Delaware False Claims and Reporting Act, 6 Del. Code Ann. § 1431(a)(1) and (2)," but no such provision exists in the Delaware code. I assume that the relators intended to cite to the Delaware False Claims and Reporting Act, 6 Del. Code Ann. § 1201(a)(1) and (2). The relators also raise a claim under N.H. Rev. Stat. Ann. § 167:61(1)(a)–(b) (2009), a provision that was repealed effective January 1, 2010. 2004 N.H. Laws ch. 167 page 509. However, a private individual may file a false claims action under New Hampshire Revised Statute §§ 167:61-b and 167:61-c, which effectively replaced § 167-61 and was effective as of January 1, 2005. I assume that the relators intend to raise a claim under the latter, active statute.

that Medtronic unlawfully terminated her in retaliation for filing the instant action. (Consol. Compl. at 88–90.) In their prayer for relief, the relators seek up to treble damages for each violation under the federal and state statutes for fraudulently submitted reimbursement claims, an injunction ordering Medtronic to cease its fraudulent activity, and reinstatement of Nowak with appropriate back pay and damages. (Consol. Compl. at 90–94.)

Medtronic moved to dismiss the Consolidated Complaint for lack of subject matter jurisdiction, lack of standing as to relator Dodd, and failure to state a claim. *See* Fed. R. Civ. P. 12(b)(1) and (6). Medtronic also seeks dismissal for failure to comply with the particularity requirement of Federal Rule of Civil Procedure 9(b). I will address each challenge in turn.

III. ANALYSIS

A. Dismissal for Lack of Jurisdiction

At the outset, "[t]he threshold question in a False Claims Act case is whether the statute bars jurisdiction." *Duxbury*, 579 F.3d at 20 (quoting *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir. 2007)). Whether a relator is qualified to bring a *qui tam* action under the FCA is a question of subject matter jurisdiction. *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 468 (2007). The relators, "as the proponent[s] of federal jurisdiction, bear[] the burden of

proving its existence by a preponderance of the evidence." *Poteet*, 619 F.3d at 109. A relator's eligibility to assert each claim alleged in the complaint must be examined separately, with only those claims that a relator is eligible to bring surviving the motion to dismiss on these grounds. *Rockwell Int'l Corp.*, 549 U.S. at 476.

In determining whether subject matter jurisdiction lies, I look to the Consolidated Complaint. *Id.* at 473–74. However, "[w]hen evaluating a 12(b)(1) motion to dismiss, the court may conduct a 'broad inquiry' and may consider extrinsic materials, including exhibits attached to the pleadings and the evidentiary materials submitted by the parties." *In re Pharm. Indus. Average Wholesale Price Litig.*, 538 F. Supp. 2d 367, 375 (D. Mass. 2008) (quoting *Hernandez-Santiago v. Ecoloab, Inc.*, 397 F.3d 30, 33 (1st Cir. 2005)). Furthermore, "[t]he basis for jurisdiction must be apparent from the facts existing at the time the complaint is brought." *United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 510 (6th Cir. 2009) (citing *Steel Co. v. Citizens for Better Env't*, 523 U.S. 83, 94–95 (1998)). I must accept as true all well-pleaded facts and resolve all reasonable inferences in the relators' favor. *Cooperman v. Individual, Inc.*, 171 F.3d 43, 46 (1st Cir. 1999). Accordingly, I will consider the consolidated complaint, the relators' original complaints where relevant, and materials submitted by

the parties in relation to the motion to dismiss.

Medtronic argues that this court lacks jurisdiction over the relators' FCA claims on several grounds. Medtronic first contends that the FCA's public disclosure bar, 31 U.S.C. § 3730(e)(4), precludes this court from exercising subject matter jurisdiction over this action. Medtronic then argues that Dodd's False Claims action, which was filed one year after Nowak's, is barred by the FCA's first-to-file requirement, 31 U.S.C. § 3730(b)(5). Finally, Medtronic argues that Dodd lacks standing to bring an FCA claim against Medtronic in this matter because he signed a termination agreement that contained an expansive release of claims.

As discussed below, I find that prior disclosures of the fraud allegations triggered the public disclosure bar but that relator Nowak qualifies as an original source with respect to the alleged off-label promotion scheme. By contrast, I find that relator Dodd does not qualify as an original source regarding any claim asserted in the Consolidated Complaint. Moreover, Dodd's FCA action is barred by the FCA's first-to-file rule and by the release of claims he signed prior to filing his complaint.

1. Public Disclosure Bar

As previously noted, the FCA mandates that a court has no jurisdiction over "an action . . . based upon the public disclosure of allegations or transactions" in various

proceedings, reports, investigations, or the news media. 31 U.S.C. § 3730(e)(4)(A).[8] In determining whether the public disclosure bar precludes a given claim, I must engage in a three-part inquiry focusing on "(1) whether there has been a prior, public disclosure of fraud; (2) whether that prior disclosure of fraud emanated from a source specified in the statute's public disclosure provision; and (3) whether the relator's *qui tam* action is 'based upon' that prior disclosure of fraud." *Poteet*, 619 F.3d at 109 (citing *United States ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 53 (1st Cir. 2009)). A negative answer to any one of these inquiries renders the public disclosure bar inapplicable. *Id.* However, "if all three questions are answered in the affirmative, the public disclosure bar applies unless the relator qualifies under the 'original source' exception" as defined by 31 U.S.C. § 3730(e)(4)(B). *Id.* at 109–10.

a. Public Disclosures

The First Circuit has held that "[a] prior, public disclosure of fraud occurs 'when the essential elements exposing the particular transaction as fraudulent find their way into the

[8]PPACA amended § 3730(e)(4)(A) in March 2010 to state that "[t]he court shall dismiss an action or claim under this section, unless opposed by the Government, *if substantially the same allegations or transactions as alleged in the action or claim* were publicly disclosed." PPACA § 10104, 124 Stat. at 901 (emphasis added). Although PPACA is not retroactive, the following analysis establishes that the public disclosure bar applies in this case under either version of the provision.

public domain.'" *Id*. at 110 (quoting *Ondis*, 587 F.3d at 54). This is because, once "the materials necessary to ground an inference of fraud are generally available to the public, . . . there is nothing to prevent the government from detecting it" and pursuing it. *Id.* at 111. A "public" disclosure is one "generally available to the public," *id.*, meaning "the public outside of the government," *Ondis*, 587 F.3d at 55 (citation omitted). To be considered a disclosure "'of fraud' the public disclosure must contain either (1) a direct allegation of fraud, or (2) both a misrepresented state of facts and a true state of facts so that the listener or reader may infer fraud." *Poteet*, 619 F.3d at 110 (citations omitted). In the second option, "[t]he two states of facts may come from different sources, as long as the disclosures together lead to a plausible inference of fraud." *Ondis*, 587 F.3d at 54. However, there is no public disclosure when the "essential background information" is publicly available but no allegation of fraud or true state of facts has been made publicly available. *United States ex rel. Ven-A-Care of Fla. Keys, Inc. v. Actavis Mid Atl. LLC*, 659 F. Supp. 2d 262, 266–68 (D. Mass. 2009).

Medtronic has produced sufficient evidence of public disclosure in the news media and by the government of the allegations of fraud by Medtronic to establish that there was prior public disclosure. The sources disclose "direct

allegation[s] of fraud" as well as both a "true state of facts" and a "false state of facts" sufficient to infer the fraudulent schemes of both false certification and off-label promotion by Medtronic.

First, it is clear that the government, the medical community, and the media were aware of off-label promotion of biliary stents for use in the vascular system prior to the filing of both relators' complaints. The Consolidated Complaint itself relies heavily on a 2008 article in the *American Journal of Therapeutics* that discusses the dangers of the widespread off-label use of the biliary stents in the vasculature. (Consol. Compl. ¶¶ 137–38.) The government's concern and investigation was also public knowledge. The DHHS issued a Warning Letter to Cordis for off-label advertising of its biliary stent in 1999, and Medtronic recalled its Assurant biliary stent in 2003 due to concerns arising from off-label use in the vasculature. (Consol. Compl. ¶ 126; Nemirow Decl., Ex. H.) The FDA called a meeting of all biliary-stent manufacturers in March 2007 to warn against off-label use *and promotion* of biliary stents. (Nemirow Decl., Ex. K.) According to one media report of the meeting, "[o]n its web sit[e], the FDA stated that the March [2007] meeting was the result of an investigation 'prompted by the promotion of metal biliary stents for vascular indications.'" (Nemirow Decl., Ex. K.) Another industry publication reported in March 2007 that the

"FDA says that manufacturers have encouraged off-label implants by marketing biliary stents for vascular indications on their Web sites and at meetings." (Nemirow Decl., Ex. L.) News media also reported that the FDA was investigating biliary-stent producers for off-label promotion: "The U.S. Department of Justice is conducting a civil investigation of allegations that Boston Scientific and other suppliers improperly promoted biliary stents for off-label uses." (Nemirow Decl., Ex. M.) Both the publications by the FDA on its website and the media coverage of the meeting constitute public disclosures.

Second, the news media raised direct allegations of fraud with respect to both the off-label promotion of biliary stents and the misuse of the 510(k) clearance process to enable off-label use. A May 16, 2007, article in *Lawyers & Settlements* stated that "the FDA has known about the rampant off-label sales of bile stents for years and this is another example of how the nation's regulatory watchdog has failed to protect consumers from the profit driven pharmaceutical industry." (Nemirow Decl., Ex. K.) The article continued, "[T]he profit-driven sales of devices for unapproved uses may be nearing the end because law enforcement agencies are warning that off-label marketing will continue to be a focus of anti-fraud enforcement efforts over the next two years." (Nemirow Decl., Ex. K.) A *New York Times* article provided facts that give rise to an inference that, given

the market realities, biliary stents were intended and cleared for off-label use. (Nemirow Decl., Ex. O.) The article reported that off-label uses of biliary stents account for ninety percent of the market for those devices and that, whereas the off-label use is a multi-billion dollar industry, the market for on-label use is relatively small. (Nemirow Decl., Ex. O.) The article also stated that a new device by Medtronic (the Complete SE) was cleared in November 2007, despite concerns regarding off-label use and promotion. (Nemirow Decl., Ex. O.) These facts, *inter alia*, certainly "contained enough information to enable the government to pursue an investigation against [Medtronic]" for both the false-certification and off-label promotion schemes. *United States v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1019 (9th Cir. 1999).

The relators argue that industry-wide suspicion alone is not sufficient to constitute a public disclosure with respect to Medtronic. This argument fails for several reasons. First, several of the disclosures identify Medtronic. Media reports of the March 2007 FDA-called meeting state that Medtronic was in attendance. (Nemirow Decl., Ex. L.) Other media reports on off-label promotion recognize Medtronic as a significant biliary-stent manufacturer. (Nemirow Decl., Ex. M.) The *New York Times* identified Medtronic's Complete SE device as the latest device cleared in relation to the off-label promotion and off-label use

issue. (Nemirow Decl., Ex. O.) Second, even though the *New York Times* article is the only media source entered into the record that suggests impropriety specifically by Medtronic, the repetitive mention of Medtronic in these public disclosures of uniform off-label promotion provides enough evidence to identify Medtronic as a perpetrator of the allegedly industry-wide fraud. *See United States ex rel. Gear v. Emergency Med. Assocs. of Ill., Inc.*, 436 F.3d 726, 729 (7th Cir. 2006) ("Industry-wide public disclosures bar *qui tam* actions against any defendant who is directly identifiable from the public disclosures.");[9] *United*

[9]The Seventh Circuit has recently clarified its opinion in *United States ex rel. Gear v. Emergency Medical Associates of Illinois, Inc.*, 436 F.3d 726, 729 (7th Cir. 2006). In *United States ex rel. Baltazar v. Warden*, 635 F.3d 866, 869 (7th Cir. 2011), the court distinguished between a public disclosure "identifying a *uniform* practice," as in *Gear*, from one "disclosing that some but not all firms use a practice." In *Baltazar*, the disclosures stated that half of all chiropractic claims are fraudulent but did not identify the defendants as among the fifty percent of chiropractors participating in the fraud. *Id.* at 867–68. Therefore, the Seventh Circuit held, "[b]y placing defendants among the perpetrators of fraud, [the relator] performed the service for which the False Claims Act extends the prospect of reward (if the allegations are correct)." *Id.* at 868. Unlike *Baltazar*, the disclosures submitted by Medtronic do identify Medtronic as among the likely perpetrators of the industry-wide false-certification and off-label-promotion schemes. Moreover, this disclosure is sufficient to satisfy the First Circuit's somewhat broader interpretation of public disclosures as disclosures that "together lead to a plausible inference of fraud." *United States ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 54 (1st Cir. 2009); *see also Poteet*, 619 F.3d at 110 (concluding that a public disclosure occurs "when the essential elements exposing the particular transaction as fraudulent find their way into the public domain").

States ex rel. Findley v. FPC-Boron Emps.' Club, 105 F.3d 675, 688 (D.C. Cir. 1997) (finding the disclosure bar to apply when the "relator['s] complaint merely echoes publicly disclosed, allegedly fraudulent transactions that already enable the government to adequately investigate the case and to make a decision whether to prosecute, the public disclosure bar applies" even when the defendant-in-suit was not named in the disclosures); *see also Ven-A-Care of Fla. Keys*, 659 F. Supp. 2d at 268 (recognizing a permissible inference that industry-wide public disclosure bars a defendant–member of that industry when there is a "narrow class of suspected wrongdoers" (citation and internal quotation marks omitted)). Additionally, as the Consolidated Complaint alleges, one of Medtronic's biliary stents was recalled in 2003 due to off-label use. (Consol. Compl. § 126.)

The public disclosures, therefore, explicitly link Medtronic to both the allegedly fraudulent off-label promotion and false-certification schemes. And, consequently, public disclosures predating Nowak's original March 5, 2008, complaint fairly encompass the relators' allegations.

Although the relators' complaints undoubtedly provide more detailed information than do the public disclosures, the allegations disclosed publicly need not be identical to or as detailed as the allegations contained in the complaint. *Dingle*

v. Bioport Corp., 388 F.3d 209, 214–15 (6th Cir. 2004) ("So long as the government is put on notice to the potential presence of fraud, even if the fraud is slightly different than the one alleged in the complaint, the *qui tam* action is not needed."). In *Dingle*, the Sixth Circuit found that a single congressional witness's testimony that the defendant fraudulently modified production of a drug, albeit on different grounds than those asserted by the relators, constituted public disclosure of fraud. *Id.* at 214.

This is not a case in which the public disclosures asserted only "essential background information" or "lack[ed] any suggestion of fraudulent activity by drug manufacturers or anyone else . . . or any indication of how the scheme works." *Ven-A-Care of Fla. Keys*, 659 F. Supp. 2d at 266–68 (declining to find public disclosure when neither the defendants nor the drugs at issue were revealed in the published government reports at issue). Public disclosures here described an industry–wide practice of off-label promotion and misuse of the 501(k) certification process relating to biliary stents and specifically identified Medtronic — and more than one of its biliary stent products — as complicit in this scheme.

b. Statutorily Recognized Sources of Public Disclosure

The public disclosure bar applies to public disclosures that occur "in a criminal, civil, or administrative hearing, in a

congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media." 31 U.S.C. § 3730(e)(4)(A). On its face, the statute encompasses government investigations such as the FDA's. Additionally, the majority of the public disclosures of fraud in this case appear in industry or national news media. (*See* Nemirow Decl., Exs. J–P.) Because "[a]ny transactions and allegations discussed in the news media would seem to qualify as public disclosures," *Poteet*, 619 F.3d at 110, I answer the second inquiry in the public-disclosure-bar analysis in the affirmative.[10]

c. "Based Upon" Public Disclosure

I must next determine whether the relators' action is "based upon" the public disclosures. *See* 31 U.S.C. § 3730(e)(4)(A). An action is "'based upon' prior disclosures if the relator's complaint contains allegations that are 'substantially similar to' those disclosures." *Poteet*, 619 F.3d at 114 (quoting *Ondis*, 587 F.3d at 58). Even if it is clear from the record that the allegations made in the Consolidated Complaint did not derive from the public disclosures but from information gained from the relators' own experiences, First Circuit case law holds that

[10]In March 2010, PPACA amended the statutory sources listed in § 3730(e)(4)(A). However, the statute as amended still covers government investigations and news media sources, and so the application of PPACA would not affect my determination of this inquiry.

their claims were "based upon" the public disclosures if they were "substantially similar." *Ondis*, 587 F.3d at 58. When making this determination, I "must compare the substance of the prior disclosures with the substance of the relator[s'] complaint[s]." *Poteet*, 619 F.3d at 114.

The First Circuit has not particularized how similar the claims must be to the disclosures to render them "substantially similar." In the court's two cases addressing this question, the prior disclosures were nearly identical to the claims: in *Poteet*, the disclosures consisted of prior FCA actions against the same defendant by the same relator and by another relator alleging the same fraudulent scheme, 619 F.3d at 114–15 (noting that "[t]he only notable difference between the two allegations" is that in the latest complaint, the relator identifies a specific device and the exact means by which the improper influence was applied to induce fraudulent claims); and, in *Ondis*, a previously released FOIA response "[wa]s substantially similar (indeed, identical)" to the relator's complaint, 587 F.3d at 58. In both cases, the complaints alleged more detailed facts than the disclosures, but generally described the same alleged fraud.

The public disclosures here disclosed all of the essential elements of the relators' false-certification claims, including how biliary stent manufacturers — and Medtronic in particular — used the 510(k) process to approve *de facto* vascular stents under

the less stringent guise of Class II biliary stents. One article even refers to the FDA's approval of a specific Medtronic device in 2007 (the Consolidated Complaint identifies this device as the Complete SE). (*See* Nemirow Decl., Ex. O.) As in *Poteet*, the Consolidated Complaint adds details — identifying the allegedly fraudulently certified devices and the means by which Medtronic allegedly misrepresented the stents to the FDA during the certification process — but alleges the same fraudulent scheme. *See Poteet*, 619 F.3d at 115. Consequently, under the First Circuit's interpretation of "based upon," the false-certification claims fall under the public-disclosure bar (unless the relators are otherwise exempted as original sources). *See Ondis*, 587 F.3d at 58.

The differences between the public disclosures and the Consolidated Complaint's allegations regarding off-label promotion are greater than those concerning the false-certification claims. Whereas the news articles outline precisely how biliary stent manufacturers used the 510(k) process to certify stents made for vascular usage, the articles disclosing the off-label marketing scheme make more general allegations of rampant off-label promotion by Medtronic and others and the FDA's investigations and concerns regarding the practice. By contrast, the Consolidated Complaint provides specific allegations of fraudulent conduct by Medtronic and gives

the who, when, and how regarding the workings of Medtronic's off-label marketing operation. Nevertheless, the First Circuit's interpretation of "based upon" is broadly defined; the public disclosures allege an intentional off-label promotion scheme and identify Medtronic as a likely perpetrator. The public disclosures, therefore, "ultimately target[] the alleged fraudulent scheme. That is enough to trigger the disclosure bar." *Poteet*, 619 F.3d at 115; *cf. United States ex rel. Baltazar*, 635 F.3d 866, 869 (7th Cir. 2011) (concluding that the relator's "defendant-specific" allegation was not "substantially similar" to the public disclosures because they had reported only that "false or mistaken claims are common" but did not identify the defendant as among those submitting fraudulent claims); *United States ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112, 124 (D. Mass. 2011) (finding claim "based upon" disclosures that had identified best-price manipulation scheme, how it worked, and at least some of the pharmaceuticals involved, thereby "b[ringing] to light all of the 'essential elements' of [the relator's] best price allegations"). Thus the FCA's disclosure bar applies to both of the relators' allegations here and their action must be dismissed unless the relators demonstrate that they are original sources.

d. The Original-Source Exception

An original source is "an individual who [(I)] has direct

and independent knowledge of the information on which the allegations are based and [(ii)] has voluntarily provided the information to the Government before filing an action under [the FCA] which is based on the information." 31 U.S.C. § 3730(e)(4)(B).[11]

I will address the second requirement first. The First Circuit has "h[e]ld that § 3730(e)(4)(B) only requires that a relator provide his or her information [to the government] prior to the filing of the *qui tam* suit." *Duxbury*, 579 F.3d at 28. In *Duxbury*, the court rejected the "contention that § 3730(e)(4)(B) requires an 'original source' to provide his or her information before the public disclosure at issue."[12] *Id*. The relators

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[11]PPACA amended this provision of the FCA as of March 23, 2010. *See* 31 U.S.C. § 3730(e)(4)(B), *as amended by* PPACA § 10104, 124 Stat. at 901. However, the amendments would not substantively affect my determination of either relator's qualification as a material source as to either allegedly fraudulent scheme.

[12]Circuit splits exist with respect to whether an original source must provide information to the government prior to filing a *qui tam* suit, as the First and Seventh Circuits have held, or prior to the public disclosure of the fraud and, if so, whether the information must be the source of the public disclosure itself. *See United States ex rel. McKenzie v. BellSouth Telcomms., Inc.*, 123 F.3d 935, 943 (6th Cir. 1997) (holding that an original source must provide information to the government before the public disclosure but need not be a source of the public disclosure); *United States ex rel. Dick v. Long Island Lighting Co.*, 912 F.2d 13, 16 (2d Cir. 1990) (holding that to be an original source, the relator must have directly or indirectly been a source to the entity that publicly disclosed the fraud). The defendant in *United States ex rel. Duxbury v. Ortho Biotech Prods. L.P.*, 579 F.3d 13 (1st Cir. 2009) petitioned for a writ of *certiorari* on this issue, but the petition was denied. *Ortho Biotech Prods., L.P. v. United States ex rel. Duxbury*, 130 S. Ct.

concede that Dodd only provided the government with information "concurrent with his filing." (Opp. at 19 n.84.) No further details regarding what he disclosed, to whom, or how are provided. "Concurrent" is not "before" and, consequently, Dodd fails to qualify as an original source. Accordingly, all claims attributable to Dodd will be dismissed.

Nowak, however, disclosed her allegations to the government on November 9, 2007, and February 29, 2008.[13] (Stevenson Decl. ¶ 2.) She also claims that she submitted a draft of her original complaint to the government on November 16, 2007, prior to filing her *qui tam* action. (Stevenson Decl. ¶ 4.) Although the details of the information provided are not alleged, provision of a draft copy of the original complaint, in addition to several conversations, complies with the strict letter of the statute, which requires only that the original source "voluntarily provide[] the information to the Government before filing an action." 31 U.S.C. § 3730(e)(4)(B); *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, — F.3d —, 2011 WL 2150191, at *6 n.8 (1st Cir. June 1, 2011) ("Hutcheson's complaint stated

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3454 (2010).

[13]Nowak's counsel contacted the United States Attorney's Office in Boston, Massachusetts, on November 9 and 16, 2007, to discuss Nowak's allegations. (Stevenson Decl. ¶¶ 2–3.) He then contacted the same office on February 29, 2008, at which point Nowak personally discussed her claims with the government. (Stevenson Decl. ¶ 5.)

that she disclosed the allegations to the United States Attorney's Office . . . in the 'Summer of 2006' 'prior to filing.' This is more than enough."); *Baltazar*, 635 F.3d at 869.

The original-source exception also requires Nowak to demonstrate that she "has direct and independent knowledge of the information on which the allegations are based." 31 U.S.C. § 3730(e)(4)(B). In order to do so, she must provide more than mere "conclusory allegations" in the complaint. *Duxbury*, 579 F.3d at 28. The Supreme Court has held that "the 'information' . . . is the information upon which the relator's allegations are based." *Rockwell Int'l Corp.*, 549 U.S. at 470–71. "A relator's knowledge is 'direct' if she acquired it through her own efforts without an intervening agency, and it is 'independent' if her knowledge is not dependent on the public disclosure." *In re Pharm. Indus. Average Wholesale Price Litig.*, 538 F. Supp. 2d at 379 (citation omitted).

Nowak's original, amended, and consolidated complaints allege the off-label promotion scheme with great detail. She refers to specific emails, conversations, meetings, promotional materials, and sales reports to support her allegations. These are materials that she collected as a Medtronic sales representative and not from public disclosures or another source. *See United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 694 F. Supp. 2d 48, 60 (D. Mass. 2010), *rev'd on other grounds*, 2011

WL 2150191 (1st Cir. 2011) (finding that a relator was an original source because, as the defendant's employee, "she observed [the defendant's] business practices[,] . . . was privy to meetings, conversations, and other internal communications[, and] . . . had access to email and internal documents and data which reflected the conduct discussed in the complaint"). As to the off-label promotion scheme, Medtronic's assertions that Nowak based her allegations on information available publicly is simply not supported by the record.

Nowak's original and amended complaints, however, do not establish that she was an original source for the alleged false-certification scheme. Although she implies that Medtronic designed its biliary stents only for vascular stents and submitted false certifications to clear those stents, the detailed first-hand description of that scheme originated with Dodd, who is otherwise disqualified as an original source.

e. Conclusion

In conclusion, I find that the public disclosure bar applies to allegations contained in the Consolidated Complaint. Furthermore, I have determined that Dodd fails to qualify as an original source and that all claims attributable to him must be dismissed on this ground. With respect to the off-label promotion allegation only, I find that Nowak qualifies as an original source and, consequently, that this claim survives the

jurisdictional bar of § 3730(e)(4). The false certification allegation, however, will be dismissed.

2. First-to-File Requirement

Even if Dodd did qualify as an original source regarding any of the allegations in the Consolidated Complaint, his False Claims Act action is barred by the FCA's first-to-file requirement. Once a relator files a *qui tam* action under the FCA, "no person other than the government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). This jurisdictional bar serves the dual purpose of preventing parasitic claims based on allegations already available to the government and of avoiding duplicative suits. *Duxbury*, 579 F.3d at 32. This first-to-file requirement is "exception–free." *Id.* at 33 (citation omitted).

The First Circuit has held that § 3730(b)(5) "bar[s] a later allegation [if it] states all the *essential facts* of a previously-filed claim or the *same elements* of a fraud described in an earlier suit." *Id*. at 32 (citation and internal quotation marks omitted) (emphases and alterations in original). According to the "'essential facts' standard, § 3730(b)(5) can still bar a later claim 'even if that claim incorporates somewhat different details.'" *Id.* (quoting *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 232–33 (3d Cir. 1998)). Consequently, in considering Medtronic's argument

that Nowak's April 17, 2008, Amended Complaint bars Dodd's subsequent April 16, 2009, complaint, I must compare the two complaints. *See LaCorte*, 149 F.3d at 234 n.6; *see also Duxbury*, 149 F.3d at 33 (stating that § 3730(b)(4) "does not permit us to consider the Information, which was provided after the filing of the [second-filed] Complaint").

The relators acknowledge that Dodd's and Nowak's allegations of fraud are similar, but contend that Dodd disclosed additional "essential facts," namely (1) "critical facts" regarding Medtronic's scheme to clear as biliary what were really vascular stents, (2) that Medtronic executives ignored Dodd's protests regarding clearance instead of premarket approval of the stents, and (3) that Medtronic used Clinical Advisory Boards to promote off-label use of its biliary stents. The second disclosure is not an "essential fact" to Dodd's FCA claim and is, in any case, subsumed by Nowak's ample evidence of Medtronic management's dismissals of objections to the unlawful off-label promotion and use of biliary stents. (*See, e.g.*, Nowak, Am. Compl. ¶¶ 67, 72; Nowak Compl. ¶¶ 64, 69.) Nowak's Amended Complaint makes clear that Medtronic executives and management were aware of and encouraged this alleged scheme. The third purportedly new disclosure likewise asserts no new essential facts in light of Nowak's allegations that sales representatives were urged to attend — and to encourage physician–clients to attend — various

training sessions and conferences at which biliary stents were promoted for vascular use. (Nowak Am. Compl. ¶ 66; Nowak Compl. ¶ 63.) Dodd's reference to Clinical Advisory Boards or "VIP meetings" provides additional detail, but no new essential fact.

The first alleged new disclosure also fails to break fresh ground, but the reasons this is so require more extensive discussion. Nowak's Amended Complaint asserts general allegations that Medtronic cleared vascular stents as biliary stents in order to avoid the costly and time-consuming premarket approval process. (Nowak Am. Compl. ¶¶ 50, 53–54 ("Medtronic chooses to forego this more rigorous [premarket approval] process by selling its biliary devices off-label, without government approval.").) She notes also that one promotional brochure announced the Racer stent as "the first cobalt chromium stent launched for peripheral applications," implying that the Racer was designed to function in the vasculature and not in the biliary tree. (Nowak Am. Compl. ¶ 53; Nowak Compl. ¶ 54.) Nowak also alleges with some detail that Medtronic intended to market the biliary stents exclusively as vascular stents even before those devices were cleared. (Nowak Am. Compl. ¶¶ 47–48, 53.) However, the Amended Complaint provides none of the details regarding the design or development process of the biliary devices that the Consolidated Complaint provides.

Thus, it seems apparent that the bulk of the allegations in

the Consolidated Complaint concerning Medtronic's false-certification scheme arise from Dodd's experience as a researcher and developer of the Racer and Complete SE stents. However, although the Consolidated Complaint describes the scheme through the development of these devices in considerable detail, Dodd's brief, fourteen-page original complaint only sketched the outlines of these allegations. (Dodd Compl. ¶¶ 12–28.) In particular, Dodd chronicles his work on and objections to the release of the Racer stent for use as a vascular stent (Dodd Compl. ¶¶ 12–25), as well as his subsequent discovery that other biliary stent lines were developed with the same intent and clearance procedure (Dodd Compl. ¶¶ 26–28). Oddly, Dodd did not allege in his original complaint any fraudulent or unlawful activity with respect to the Complete SE stent, although the development and clearance of that stent constitutes a significant portion of the false-certification-scheme allegation in the Consolidated Complaint, and the Complete SE was cleared by the FDA more than one year prior to the filing of Dodd's original complaint. (Consol. Compl. ¶ 74.) By contrast, Nowak's Amended Complaint did include allegations regarding the Complete SE. (Nowak Am. Compl. ¶ 48.)

Comparing the relators' individually filed complaints, it is evident that while Dodd added some detail about the false-certification scheme and clearly had access to further

information regarding the scheme, he failed to allege any new "essential facts" or "elements of the fraud" in his original complaint. Moreover, Nowak offered sufficient allegations and evidence "to put the government on notice of the essential facts of a fraudulent scheme" of false-certification. *Hutcheson*, 694 F. Supp. 2d at 57 (following *Duxbury*, 579 F.3d at 32). Dodd's claims, therefore, must be dismissed for lack of jurisdiction.[14]

3. Dodd's Release of Claims

Dodd's claims are further barred by the release that he signed as part of his termination agreement with Medtronic. Dodd signed the agreement on December 29, 2008, nearly four months *before* he filed his False Claims Act action. (Nemirow Decl., Ex. S at 8.) In the termination agreement, Dodd released Medtronic "from any and all claims of any kind, known or unknown, that arose on or before the time Dodd signed this agreement." (Nemirow Decl., Ex. S ¶ 4(a).) Those released claims "include, without limitation, any and all claims arising out of or related to his employment with the Company and his separation from

[14]The relators argue that because they have a relator-share agreement and because they submitted a consolidated complaint, Dodd cannot be dismissed from the instant action. (Opp. at 21 n.89.) This assertion is patently incorrect. Where this court lacks jurisdiction over the claims of a later-added relator due to the first-to-file rule, those claims attributable to that relator — and that relator — must be dismissed. *Duxbury*, 579 F.3d at 28–29. Whether the relator-share agreement survives the dismissal of one relator is a matter of contract between the relators.

employment with the Company." (Nemirow Decl., Ex. S ¶ 4(b).) They also "include, without limitation, . . . claims of fraud or negligent misrepresentation . . . [and] claims that he may have or assert based on alleged acts or omissions by the Company, and any other claims that are based on any alleged legal obligation of the Company." (Nemirow Decl., Ex. S ¶ 4(c).) The relators argue that the release is unenforceable with respect to his FCA claims because (1) only the government can release FCA claims and (2) public policy prohibits the release of FCA claims. Case law, however, dictates otherwise.

A relator may not enter into an enforceable settlement or release of *qui tam* claims *after* filing a False Claims Act action. *See* 31 U.S.C. § 3730(b)(1) ("The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting."); *United States ex rel. Radcliffe v. Purdue Pharma L.P.*, 600 F.3d 319, 326 (4th Cir. 2010); *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 474 (5th Cir. 2009). However, the FCA does not by terms address whether a release of claims entered into *before* filing a *qui tam* action bars subsequent *qui tam* claims.[15]

[15]Relators rely upon *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 474 (5th Cir. 2009), in arguing that Dodd's release is unenforceable due to public policy. However, *Longhi* addressed a release contained in a stock sale agreement that post-dated the filing of the *qui tam* action. It is, therefore, inapposite.

Radcliffe, 600 F.3d at 326; *United States ex rel. Ritchie v. Lockheed Martin Corp.*, 558 F.3d 1161, 1168 (10th Cir. 2009) (noting that the statute does not apply to pre-filing releases because, "[w]hen there is a release preceding the filing of the *qui tam* action, . . . no action has been filed, so there is neither an action to dismiss nor a judge to consent to the agreement"). Recent case law demonstrates that a *pre*-filing release of claims can bar a False Claims Act action in certain circumstances such as those present in the case before me here.

Courts have rejected relators' first argument: that only the government can release a defendant from *qui tam* actions because the government — and not the relator — suffered the injury in fact. In *Radcliffe*, the Fourth Circuit found that the FCA in effect partially assigned claims of the United States to the relator. 600 F.3d at 328–29 (relying upon *Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 772 (2000) (noting that an FCA relator has Article III standing because "the [FCA] gives the relator himself an interest *in the lawsuit*, and not merely the right to retain a fee out of recovery . . . [and] provides that '[a] person may bring a civil action . . . *for the person and for the United States Government*'" (quoting 31 U.S.C. § 3730(b)(1) (emphases in original))). Because a relator has an interest in the lawsuit, he can release

that interest if public policy does not outweigh its enforcement. *Id.*

There is an emerging agreement within the Courts of Appeals that pre-filing releases bar subsequent *qui tam* claims if (1) the release can be fairly interpreted to encompass *qui tam* claims and (2) public policy does not otherwise outweigh enforcement of the release. *See, e.g.*, *Radcliffe.* 600 F.3d at 329; *Ritchie*, 558 F.3d at 1168–69; *United States ex rel. Hall v. Teledyne Wah Chang Albany*, 104 F.3d 230, 231–33 (9th Cir. 1997). The release at issue here fulfills both prongs of this inquiry.

The language of Dodd's release is sufficiently expansive to include his *qui tam* claims. The release included "any and all claims of any kind, known or unknown, that arose on or before the time Dodd signed this agreement." (Nemirow Decl., Ex. S ¶ 4(a).) The information Dodd relies upon to bring his *qui tam* claims and the fraud alleged therein were known to him before the execution of the settlement agreement and, consequently, fall within the time frame of the released claims. Additionally, Dodd released claims of "fraud," "any and all claims arising out of or related to his employment," and all claims arising under federal law. (Nemirow Decl., Ex. S ¶ 4(b)–(c).) The FCA claims fall squarely within those descriptors. *See Ritchie*, 558 F.3d at 1167 (finding a release of all claims the relator "might have under federal . . . law" to include *qui tam* claims under the FCA).

In addressing the second prong – concerning public policy – courts have applied the balancing test laid out by the Supreme Court in *Town of Newton v. Rumery*, 480 U.S. 386, 392 (1987). *See Radcliffe*, 600 F.3d at 327; *Longhi*, 575 F.3d at 474; *Ritchie*, 558 F.3d at 1169; *United States ex rel. Gebert v. Transp. Admin. Servs.*, 260 F.3d 909, 916 (8th Cir. 2001). In *Rumery*, the Court held that "a promise is unenforceable if the interest in its enforcement is outweighed in the circumstances by a public policy harmed by the enforcement of the agreement." 480 U.S. at 392. Courts engaging in this balancing test in the FCA context have generally "appl[ied] the analytical framework established by the Ninth Circuit in [*United States ex rel. Green v. Northrop Corp.*, 59 F.3d 953 (9th Cir. 1995),] and *Hall*." *Radcliffe*, 600 F.3d at 329 (collecting cases). In so doing, courts balance the "public interest in having information brought forward that the government could not otherwise obtain" with the public interest in "encouraging parties to settle disputes." *Hall*, 104 F.3d at 233 (citation omitted).

In *Green*, the Ninth Circuit applied the *Rumery* analysis and declined to enforce the agreement because the "government only learned of the allegations of fraud and conducted its investigation *because of the filing of the qui tam complaint*." 59 F.3d at 966 (emphasis in original). Therefore, in that circumstance, the public interest in unearthing fraud against the

government outweighed the public interest in private settlement of disputes. *Id.* at 969. In the subsequent *Hall* decision, the same court considered a pre-filing agreement entered into *after* the government had full knowledge of the allegations and had investigated them. 104 F.3d at 231. The *Hall* court found the public interest in encouraging relators to bring FCA claims to expose government fraud — rather than to settle privately — and "supplement federal enforcement of the FCA" was not implicated. *Id.* at 233. Accordingly, the court concluded that "[t]here are no . . . similar federal concerns [like those in *Green*] that would justify overriding the general policy in favor of encouraging parties to settle disputes." *Id.* The Tenth and Fourth Circuits have followed the Ninth Circuit's lead in *Green* and *Hall*.[16] *See Radcliffe*, 600 F.3d at 332–33 (holding that, under *Rumery*, pre-filing releases should be enforced "when . . . the government was aware, prior to the filing of the *qui tam* action, of the fraudulent conduct represented by the relator's allegations"); *Ritchie*, 558 F.3d at 1170 ("Enforcing releases of

[16]*Ritchie* and *Radcliffe* disagree on the timing of the government's knowledge — *i.e.*, whether the government must be aware of the allegations before the relator files the claim or before the relator releases the claims. *United States ex rel. Radcliffe v. Purdue Pharmra L.P.*, 600 F.3d 319, 332–33 (4th Cir. 2010); *United States ex rel. Ritchie v. Lockhead Martin Corp.*, 558 F.3d 1161, 1170 (10th Cir. 2009). Because the government knew of the allegations against Medtronic prior to the execution of Dodd's release *and* before the filing of his claim, I need not address that disagreement in this case.

qui tam claims only when the allegations of fraud have been disclosed to the government before the release also has the benefit of encouraging voluntary disclosure by government contractors."); *see also Gebert*, 260 F.3d at 916–17 (applying *Rumery* and enforcing a release of *qui tam* claims entered into during bankruptcy proceedings).[17]

I am satisfied that the inquiry laid out by the Ninth Circuit and followed by the Fourth and Tenth Circuits is consistent with § 3730(b) and with *Rumery*. Accordingly, I will adopt that approach. The case before me here is far more similar to the *Hall*, *Radcliffe*, and *Ritchie* cases than it is to *Green*. Dodd signed the settlement agreement before filing his *qui tam* action. (*Compare* Nemirow Decl., Ex. S, *with* Dodd Compl.) As discussed above, the FDA was aware of the allegations of off-label promotion and clearance of vascular stents as biliary stents prior to both the execution of the agreement in December 2008 and the filing of Dodd's original complaint in April 2009.

[17]Several other cases have assumed without expressly holding that pre-filing releases that fairly encompass *qui tam* claims bar such claims. *See, e.g.*, *United States ex rel. Whitten v. Triad Hosp., Inc.*, 210 F. App'x 878, 882 (11th Cir. 2006) (finding that a general release did not bar FCA claims because the release did not apply to the defendant–entity, but implying that had the release applied to the defendant, the FCA claim would have been barred by it); *United States ex rel. LaValley v. First Nat'l Bank of Boston*, No. 86-236-MLW, 1994 WL 601874, at *3 (D. Mass. Oct. 13, 1994) (denying a motion to substitute a relator because that relator was a straw man for an individual barred from bringing a *qui tam* action against defendant due to a previously executed release of all claims).

Moreover, the FDA was already investigating these allegations against Medtronic by the summer of 2008, following the filing of Nowak's *qui tam* action. (Nemirow Decl., Ex. T.) Accordingly, the public interest in bringing fraud against the government to light is greatly diminished and, ultimately, outweighed by the public interest in encouraging private settlement of claims. Consequently, Dodd's release strips him of standing to bring his False Claims Act action and that action must be dismissed.

B. Dismissal for Failure to State a Claim

In order to survive a motion to dismiss for failure to state a claim for which relief can be granted, Fed. R. Civ. P. 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citation and internal quotation marks omitted). The Supreme Court has held that compliance with this initial threshold requires only "a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombley*, 550 U.S. 544, 555 (2007) (interpreting Fed. R. Civ. P. 8(a)) (citation and internal quotation marks omitted). All factual allegations in the complaint must be taken as true and all reasonable inferences

drawn in the pleader's favor. *SEC v. Tambone*, 597 F.3d 436, 441 (1st Cir. 2010) (*en banc*).

1. Nowak's FCA Retaliation Claim (Count XV)

Nowak alleges that Medtronic violated the FCA by terminating her and "otherwise discriminating and retaliating against her" because of steps she took to stop violations of the FCA. (Consol. Compl. ¶ 340.) The retaliatory actions that Nowak alleges include: (1) placing her "on probation" and establishing a Performance Improvement Plan with unachievable targets on February 6, 2009; (2) establishing a second Performance Improvement Plan on May 8, 2009; (3) splitting Nowak's sales territory and withholding resources necessary for her to achieve the targets set out in the plan; and (4) terminating her on August 4, 2009. (Consol. Compl. ¶¶ 161–70.) Medtronic took these actions, Nowak suggests, because she filed her FCA action on March 5, 2008. (Consol. Compl. ¶ 160.)

Because the applicable statute was amended after the first three alleged retaliatory actions took place but before Nowak was terminated, I must first determine which version of the statute applies. Before Congress amended this provision in FERA, effective May 20, 2009, the statute protected

> an employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer *because of lawful acts done by the employee . . . in furtherance of an action under this section*, including investigation for,

> initiation of, testimony for, or assistance in an action filed or to be filed under this section.

31 U.S.C. § 3730(h) (emphasis added). Post-amendment, the statute protects "an employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee . . . *in furtherance of other efforts to stop 1 or more violations of* [*the FCA*]." 31 U.S.C. § 3730(h)(1), *as amended by* FERA, § 4(d), 123 Stat. at 1624–25 (emphasis added).

In this case, which statute I apply makes no substantive difference. Although other circuits have required a nexus between actual FCA litigation and the employee's "protected activity," the First Circuit has not. The First Circuit's more expansive definition of "protected conduct" is "activities that reasonably could lead to an FCA action[,] in other words, investigations, inquiries, testimonies or other activities that concern the employer's knowing submission of false or fraudulent claims for payment to the government." *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 237 (1st Cir. 2004) (citation and internal quotation marks omitted); *cf. United States ex rel. Sanchez v. Lymphatx, Inc.*, 596 F.3d 1300, 1303 (11th Cir. 2010) (*per curiam*) (applying the pre-FERA statute and requiring a litigation nexus); *see also Bell v. Dean*, No. 09–cv-1802-WKW, 2010 WL 2976752, at *1 (M.D. Ala. July 27, 2010)

(comparing the scope of § 3730(h) pre- and post-FERA). Therefore, whether the conduct actually led to or arose from the filing of an FCA action does not directly impact whether the conduct is "protected conduct" in this circuit. *See United States ex rel. Gobble v. Forest Labs., Inc.*, 729 F. Supp. 2d 446, 449 (D. Mass. 2010) (applying the standards laid out by the First Circuit with respect to pre-FERA § 3730(h) to an allegation subject to post-FERA § 3730(h)(1)). I will therefore apply the standards laid out by the First Circuit under pre-FERA § 3730 because the standards are essentially the same.

In order to make out a *prima facie* case of retaliation under § 3730(h) or § 3730(h)(1), a relator "must show that 1) the employee's conduct was protected under the FCA; 2) the employer knew that the employee was engaged in such conduct; and 3) the employer discharged or discriminated against the employee because of his or her protected conduct." *Karvelas*, 360 F.3d at 235 (citations omitted).

As previously stated, "protected conduct" includes "activities that reasonably could lead to an FCA suit[,] in other words, investigations, inquiries, testimonies or other activities that concern the employer's knowing submission of false or fraudulent claims for payment to the government." *Id.* at 237.

Certainly, Nowak's filing of this FCA action constitutes protected conduct under both versions of that provision. She filed her original complaint on March 5, 2008. According to the Consolidated Complaint, she received a company-wide "preservation of documents" notification, which, Medtronic informed its employees, was in response to a subpoena of "documents relating to biliary stents" that was issued by the U.S. Attorney's Office in the District of Massachusetts. (Consol. Compl. ¶ 159.) At that time, Nowak alleges, she also reviewed a document entitled "Voice Your Concern," which, in part, explained "various provisions of the [FCA] and its applicability to Medtronic." (Consol. Compl. ¶ 159.) Nowak alleges that "[d]uring the months that follow[ed]" the notification, "Medtronic developed a plan and a pretext to terminate [her] as a result of her protected activity." (Consol. Compl. ¶ 160.) Thus, although Nowak has not specifically pled which of her actions she considers to be the "protected conduct" triggering the protections of § 3730(h), I assume that she refers here to the filing of her FCA complaint.[18]

[18]Nowak also describes previous instances in which she challenged Medtronic's off-label promotion activities, refused to engage in those activities, spoke with in-house council about her concerns, and expressed concerns about her own legal liability should she engage in off-label promotion. However, she does not allege that her concerns or objections "concern[ed] the employer's knowing submission [or cause of submission] of false or fraudulent claims for payment to the government." *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 237 (1st Cir. 2004). Consequently, her complaints and objections alone do not constitute "protected conduct" under § 3730(h). *See*

The next inquiry is whether Medtronic knew of Nowak's protected conduct; that is, did Medtronic know that Nowak initiated an FCA action against it. *See Karvelas*, 360 F.3d at 235. Knowledge, in this context, means that "the employer must be on notice that the employee is engaged in conduct that 'reasonably could lead to a False Claims Act case.'" *Id.* at 238 (citation omitted). However, "the employer need not know that the employee has filed or plans to file a *qui tam* action, nor even necessarily be aware of the existence of the FCA." *Id.*

I am satisfied that Nowak has adequately pled that Medtronic was on notice that her conduct could lead to an FCA action. Nowak does not aver that Medtronic knew of her complaint, and her complaint remained sealed from Medtronic until after Nowak's termination. However, Nowak's allegations and circumstantial evidence pled in the Consolidated Complaint are sufficient at this motion-to-dismiss stage to make it "plausible on its face" that Medtronic knew that Nowak's actions were related to the subpoena that alerted Medtronic to the investigation. *See* Fed. R. Civ P. 8(a) (requiring "a short and plain statement of the

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id. ("[C]orrecting regulatory problems . . . is not actionable under the FCA in the absence of actual fraudulent conduct." (citation and quotation marks omitted)). *But see United States ex rel. Gobble v. Forest Labs., Inc.*, 729 F. Supp. 2d 446, 450 (D. Mass. 2010) (finding that relator's complaints to the defendant regarding defendant's regulatory violations, but not including concerns regarding fraud on the government, were sufficient to constitute "protected conduct" at the motion-to-dismiss stage).

claim showing that the plaintiff is entitled to relief"). Medtronic's management had arranged for Nowak to speak with both in-house and independent counsel regarding her concerns and knew that her concerns were on-going because her quarterly reports indicated that she would not sell off-label devices. As of July 2008, Medtronic knew that an active investigation of their biliary stents had been initiated and that the investigation either was or may be related to the FCA. Although the first overt retaliatory action against Nowak did not take place until she was put "on probation" some months later in February 2009, Medtronic Nowak's prior actions, coupled with an active subpoena, could have put Medtronic "on notice" that Nowak's conduct could lead to, or may have led to, an FCA action.

The final element of the *prima facie* case is that the employee was terminated, or retaliated against, "because of" the protected conduct. *Karvelas*, 360 F.3d at 235. To show this, Nowak must allege facts to support that "the retaliation was motivated, at least in part, by the employee's engaging in protected activity." *Id.* at 239 (quoting S. Rep. No. 99-345, at 35, *reprinted in* 1986 U.S.C.C.A.N. 5300). Nowak does not specifically allege that Medtronic established a pretext to terminate her and ultimately terminated her because she filed an FCA claim. It is equally plausible that Medtronic fired her because she refused to sell biliary stents for off-label uses,

which she had been informed was part of her job, or because she complained too much. (Consol. Compl.¶¶ 125, 149–50.) However, Nowak alleges that she was consistently one of the top six to thirteen sales representatives for Medtronic nationwide, including after she had refused to sell biliary stents for off-label uses. Just one month before Medtronic received the subpoena for documents, Nowak was praised for her continued excellent sales. (Consol. Compl. ¶ 158.) However, in February 2009, she was placed on probation in the middle of the quarter. The inferences are sufficient, at this stage in the case, to constitute an adequate pleading that Medtronic fired Nowak "at least in part" because of her "protected activity."

2. Nowak's Fraud Claims

Identifying the exact contours of Nowak's False Claims Act theory from the Consolidated Complaint is not a straightforward task. Nowak's original, individual action — the complaint that qualifies her as a relator in this action — clearly alleges that Medtronic's rampant off-label promotion activities caused the government to pay claims for nonreimbursable, unapproved uses of biliary stents. (Nowak Am. Compl. ¶¶ 3–7.) However, the addition of relator Dodd and his false-certification theory complicates the original allegation by, in part, predicating the fraudulent claims on Medtronic's alleged false statements in the applications for 510(k) certification rather than — or in

addition to — in off-label promotion activities. (*See, e.g.*, Consol. Compl. ¶ 140.) In Count I, the Consolidated Complaint claims:

> Each claim for reimbursement for use of Medtronic's biliary stents represents a false or fraudulent claim for payment given that those devices' approvals were obtained by false certifications and statements to the FDA and are thereby unapproved, were promoted off-label, and each claim based upon off label use of biliary stents constitutes a false and fraudulent claim for payment because such off-label uses are not approved for reimbursement for the federal government.

(Consol. Compl. ¶ 174.) Nevertheless, and as I previously have noted, the Consolidated Complaint can be interpreted as outlining two independent theories of liability, of which only the off-label promotion theory survives the initial jurisdictional hurdles. *See supra* Part III.A.1.

a. Stating a Claim Under the FCA

Nowak asserts claims under §§ 3729(a)(1) and (2) of the FCA and, post-FERA, the analogous §§ 3729(a)(1)(A) and (B). The pre-FERA version of the statute, which applies to claims submitted to the government prior to May 20, 2009, and June 7, 2008, respectively, *see supra* note 1, states:

> Any person who--
>
> > (1) knowingly presents, or causes to be presented, to . . . the United States Government . . . a false or fraudulent claim for payment or approval; [or]

> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; . . .
>
> is liable to the United States Government for a civil penalty . . . .

31 U.S.C. § 3729(a). Although Nowak asserts that fraudulent claims continued – and continue – to be submitted after the filing of the Consolidated Complaint in February 2010, the majority of the claims described in the Consolidated Complaint likely took place before the filing of her original complaint on March 5, 2008, or her termination from Medtronic in August 2009. (Consol. Compl. ¶¶ 170, 176.) I will therefore concentrate my analysis on the pre-FERA provisions and provide additional comment regarding the sufficiency of her pleadings post-FERA.

In order to establish liability under § 3729(a)(1), the plaintiff must demonstrate that the defendant "(1) present[ed] or cause[d] to be presented to the United States government, a claim for approval or payment, where (2) that claim is false or fraudulent, and (3) the action was undertaken 'knowingly,' in other words, with actual knowledge of the falsity of the information contained in the claim, or in deliberate ignorance or reckless disregard of the truth or falsity of that

information."[19] *Karvelas*, 360 F.3d at 225 (quoting 31 U.S.C. § 3729(a)(1)(b)).

By contrast, § 3729(a)(2) imposes liability on one who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government."[20] The Supreme Court has held that

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[19]Post-FERA, § 3729(a)(1)(A) prohibits "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval." Courts considering § 3729(a)(1)(A) post-FERA, have applied the same standards as applied to § 3729(a)(1) pre-amendment. *See, e.g.*, *United States ex rel. Bennett v. Medtronic, Inc.* ("*Bennett I*"), 747 F. Supp. 2d 745, 764 n.17 (S.D. Tex. 2010). Thus, to the extent that Nowak alleges that false claims were submitted after May 20, 2009, *see supra* note 1, the analysis for purposes of Rule 12(b)(6) and Federal Rule of Civil Procedure 9(b), *see infra* Part III.C, is the same as under the earlier iteration of the statute.

[20]Unlike FERA's amendment to § 3729(a)(1), the amendment to § 3729(a)(2) substantively alters the provision. The new § 3729(a)(1)(B) imposes liability on one who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." The amendment deleted the "to get" and "paid or approved by the government" requirements and added "material." *See Bennett I*, 747 F. Supp. 2d at 764 n.17. The materiality requirement does not alter my analysis, because the Supreme Court has held that false statements must be material and used the same standard of materiality under the prior version of the statute. *See Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 665 (2008). The deletion of "to get" and "paid by the government," however, "seems to suggest that an actual claim is required" where no such requirement existed in § 3729(a)(2). *United States ex rel. Crennen v. Dell Mktg. L.P.*, 711 F. Supp. 2d 157, 164 (D. Mass. 2010). The First Circuit did not address this issue in its most recent FCA opinions. *See New York v. Amgen Inc.*, — F.3d —, 2011 WL 2937420 (1st Cir. 2011) (addressing claims brought under state FCA statutes); *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, — F.3d —, 2011 WL 2150191, at *2 n.3 (1st Cir. 2011) (considering a motion brought under Rule 12(b)(6) in which "[n]either party argue[d] that § 3729(a)(1)(B) is

there is no presentment requirement for § 3729(a)(2) — as there is in § 3729(a)(1) — and that all that is required under § 3729(a)(2) is to demonstrate the recording of a false record with the requisite intent that it be relied upon for payment by the government when presented.[21] *Allison Engine, Co. v. United States ex rel. Sanders*, 553 U.S. 662, 669 (2008). As for the requisite intent, the Supreme Court held that under § 3729(a)(2), the defendant must have "intend[ed] the Government to rely on that false statement as a condition of payment." *Id.* at 672. However, under new § 3729(a)(1)(B), the relator need only show a "knowing" frame of mind similar to that required under § 3729(a)(1), rather than demonstrate the specific intent to defraud formerly required under § 3729(a)(2). *See* FERA, § 4(a)(1), 123 Stat. at 1621; *United States ex rel. Carpenter v. Abbott Labs., Inc.*, 723 F. Supp. 2d 395, 401–02 (D. Mass. 2010).

The First Circuit recently addressed a motion to dismiss under pre-FERA statutory provisions against a medical device manufacturer predicated on claims submitted by innocent third-party health care providers to Medicare for devices that had been sold in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C.

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relevantly different from the earlier provision").

[21]Presentment may now be a required element of § 3729(a)(1)(B). *Supra* note 20. While this required element does not alter my analysis under Rule 12(b)(6), it may do so under Rule 9(b), *see infra* Part III.C.

§ 1320a–7b. *See Hutcheson*, 2011 WL 2150191, at *1–2. In *Hutcheson*, the defendant device manufacturer allegedly induced physicians and hospitals to purchase medical devices in a manner that violated the AKS, but the physicians who eventually used — and submitted claims for reimbursement for the devices — did not necessarily know that the underlying transaction violated the AKS, which would otherwise preclude reimbursement. *Id.* The court observed that "[t]he Supreme Court has long held that a non-submitting entity may be liable under the FCA for knowingly causing a submitting entity to submit a false or fraudulent claim, and it has not conditioned this liability on whether the submitting entity knew or should have known about a non-submitting entity's unlawful conduct." *Id.* at *11. The court further recognized that "the language of the FCA 'indicate[s] a purpose to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud.'" *Id.* (quoting *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 544–45 (1943)). Consequently, "unlawful acts by non-submitting entities may give rise to a false or fraudulent claim even if the claim is submitted by an innocent party." *Id.*

The FCA cabins the fraud that is actionable under the FCA not by limiting the scope of misrepresentation or fraud that is actionable but rather by requiring a showing of both scienter — specific intent under § 3729(a)(2) pre-FERA and knowledge under

§ 3729(a)(1)(B) post-FERA — and materiality. *See id.* at 10. Accordingly, in order to determine whether Nowak has adequately pled a claim under § 3729(a)(2), I must "first address whether the claims at issue here misrepresented compliance with a precondition of payment so as to be false or fraudulent and then address whether those misrepresentations were material." *Id.* at *13; *see also New York v. Amgen Inc.*, — F.3d —, 2011 WL 2937420, at *6 (1st Cir. 2011) (affirming the approach laid out in *Hutcheson* and applying it to state FCA claims). This inquiry is "fact-intensive and context-specific." *Amgen Inc.*, 2011 WL 2937420, at *6.

Because the inquiries for both § 3729(a)(1) and (2) are essentially the same under Nowak's theory of relief, I will collapse the analysis.

b. Submission of False Claims

In the sole remaining federal FCA fraud theory, Nowak asserts that Medtronic "unlawfully creat[ed] demand in the medical community for off-label application of biliary stents" through various off-label promotional activities (brochures, targeting physicians, presentations, Clinical Advisory Boards, etc.). (Consol. Compl. ¶¶ 6, 73, 82–83, 86–89, 99.) And, she further claims, these actions "ha[ve] resulted in the submission of countless improper claims for reimbursement from federal and state health care programs . . . because reimbursement of such

off-label use is disallowed." (Consol. Compl. ¶ 140.) She argues that the biliary stents promoted off-label are "adulterated and misbranded," thereby rendering them categorically ineligible for reimbursement. She further alleges that Medtronic held out its biliary stents as effective peripheral vascular stents despite knowing that the efficacy and safety of the biliary stents in the vasculature were unproven and disputed. (Consol. Compl. ¶¶ 73, 126–29, 137–40.) She also alleges that the disproportionate use of biliary stents in this particular off-label use — as much as ninety percent of all devices — demonstrates that the majority of the biliary devices sold by Medtronic were ultimately paid for through claims submitted to the government. (Consol. Compl. ¶¶ 7, 66, 92, 140.) Finally, Nowak alleges that Medtronic submitted these false claims directly, to TRICARE/CHAMPUS and CHAMPVA, and indirectly, by causing health care providers to submit claims for reimbursement through Medicare and Medicaid. (Consol. Compl. ¶¶ 8–9, 54.)

However, Nowak does not identify any one specific claim for off-label use that was submitted to the government. Instead she alleges generally that "previously discussed sales reports document with great particularity the scores of customers across the country who have been marketed to and sold biliary stents for off-label, unapproved use." (Consol. Compl. ¶¶ 140, 175.) In

furtherance of her required factual inference, Nowak alleges that eighty percent of medical device payments are made through Medicare and Medicaid. (Consol. Compl. ¶ 92) The simple arithmetic of multiplying ninety percent of all devices being off-label by eighty percent of payments for those devices suggests a very high probability that improper claims were submitted to the government.

c. False Statements and Misrepresentations

In *Hutcheson*, the First Circuit departed from the holdings of many of its sister circuits in holding that the false statement or misrepresentation that is the premise of an FCA action need not be a certification. 2011 WL 2150191, at *11. *Hutcheson* endorsed the Ninth Circuit's determination that "'[s]o long as the statement in question is knowingly false when made, it matters not whether it is a certification, assertion, statement, or secret handshake; False Claims liability can attach.'" *Id.* (quoting *United States ex rel. Hendow v. Univ. of Pheonix*, 461 F.3d 1166, 1172 (9th Cir. 2006)). Medtronic's false statements or representations, therefore, may be informal representations to the physicians and hospitals regarding its biliary stents. Furthermore, as previously stated, any alleged false statements or misrepresentations by Medtronic are not "immunize[d]" by a submitting physician's or hospital's "representations regarding its own conduct." *Id.* at *12.

Therefore, that a physician or hospital actually believed that a biliary stent was "medically necessary" or safe and effective is not relevant to whether Medtronic itself made any false statements or misrepresentations, although it may be relevant to materiality. *See id.* at *14 (finding that whether "the claims were for services that would have been provided in the absence of the alleged AKS violations" does not speak to misrepresentation but rather to materiality).

A recent spate of off-label promotion FCA cases has revealed that developing case law, especially when involving medical devices, raises several unique challenges regarding proof of false statements or misrepresentation. *See Bennett I*, 747 F. Supp. 2d at 769–78 (discussing recent cases). In *Bennett I* and a second case brought by the same relators in the same court, *United States ex rel. Bennett v. Boston Scientific Corp.* ("*Bennett II*"), No. H-07-2467, 2011 WL 1231577 (S.D. Tex. Mar. 31, 2011), Judge Rosenthal catalogued and analyzed the recent off-label device promotion FCA cases. From her analysis — and that of the other courts that have considered off-label promotion cases under the FCA — it is evident that Nowak's off-label theory for relief under the FCA must first confront two issues: (1) unlawful off-label promotion alone cannot form the basis for an FCA action and (2) Medicare and Medicaid reimbursement for

off-label uses of medical devices is more permissive than reimbursement for off-label uses of pharmaceuticals.

I. False Acts vs. False Claims

Proof of unlawful off-label promotion alone cannot sustain a successful FCA action; the FCA does not impose liability for all fraudulent *acts*, only for fraudulent *claims*. *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995) ("[T]he statute attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment.'"); *see also United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 47 (1st Cir. 2009). For example, in *United States ex rel. Franklin v. Parke-Davis, Div. of Warner Lambert Co.*, 147 F. Supp. 2d 39 (D. Mass. 2001), Judge Saris denied a motion to dismiss an off-label FCA action in part because "the alleged FCA violation arises — not from unlawful off-label marketing activity itself — but from the submission of Medicaid claims for uncovered off-label uses *induced by Defendant's fraudulent conduct*." 147 F. Supp. 2d at 52 (emphasis added). However, she also recognized that "[a] much closer question would be presented if the allegations involved only the unlawful — yet truthful — promotion of off-label uses to physicians who provide services to patients who are covered by Medicaid . . . without any fraudulent representations by the manufacturer." *Id.*; *see also Bennett II*, 2011 WL 1231577, at *26 (granting a motion to dismiss an off-

label promotion medical device case in which there were facts alleged suggesting unlawful off-label promotion, but, among other things, "no allegation that the defendants represented that the FlexView system was FDA-approved" for the off-label use). More recently, in addressing state FCA claims regarding violations of the AKS, the First Circuit cautioned that "[e]ven if it is generally accepted that kickbacks are a species of fraud, that cannot resolve the dispute" under the state FCA statutes. *Amgen Inc.*, 2011 WL 2937420, at *6. Rather, the court continued, "[t]he question here is whether claims submitted to the seven state Medicaid programs misrepresented compliance with a precondition of payment recognized by those programs." *Id.*

Thus, while Nowak has alleged sufficient facts to suggest that Medtronic engaged in improper off-label promotion of its biliary stents, in order to state a claim for relief under the FCA, she must also allege that the promotion knowingly included false statements or misrepresentations in connection with the submission of false claims.

To that end, Nowak has alleged facts suggesting that Medtronic falsely represented the biliary stents as effective and safe for use in the vasculature by (1) inviting noted physicians to give presentations on such a use (Consol. Compl. ¶¶ 86, 89, 91); (2) promoting the stents at cardiology conventions (as opposed to gastroenterology conventions) (Consol. Compl.

¶¶ 82–83); (3) presenting the new 2003 Racer biliary stent as "Medtronic's fourth entry into the renal stenting segment" (Consol. Compl. ¶ 73); (4) promoting the Racer as a "cannibalization" of the Bridge Extra Support stent, which did have premarket approval for use in the vasculature (Consol. Compl. ¶ 73); (5) selling biliary devices through a peripheral sales group and listing the devices as "peripheral devices" in marketing materials before the government's 2007 industry-wide meeting (Consol. Compl. ¶¶ 93, 106); and, (6) exclusively using Vascular Group salespeople to sell the biliary stents after dissolving the peripheral sales group in mid-2007 (Consol. Compl. ¶¶ 93–94, 105).

However, the Consolidated Complaint also alleges facts suggesting that Medtronic did not conceal that the biliary stents were not FDA-approved for use in the vasculature: (1) since 1999, all biliary stents included a biliary-only indication on the labels and a warning that the stents were not known to be safe for vascular use (Consol. Compl. ¶ 37); (2) on August 31, 2007, Medtronic sent its customers a letter advising that the "FDA recently met with all of the manufacturers of biliary stents expressing concern about reports of serious adverse events associated with off-label use of biliary stents in conjunction with vascular therapy, including death, seizure, stroke, thrombosis, and vessel perforation" and stating that Medtronic's

biliary stents were only approved for "palliation of malignant neoplasm in the biliary tree" (Consol. Compl. ¶ 129); and (3) on September 13, 2007, Nowak's regional sales manager emailed her sales group and instructed them to remind physicians that the biliary stents were not approved for vascular use and that Medtronic could not guarantee the safety of the devices used in the vasculature (Consol. Compl. ¶ 132).

The factual allegations of the instant complaint should be read in light of the *Bennett* cases, in which the court granted motions to dismiss in large part because the relators did not allege that the off-label promotion included any statement – let alone a false statement – representing the off-label procedure as safe and effective. *See Bennett II*, 2011 WL 1231577, at *27 ("The authorities cited by the relator do not provide a basis to infer that a reimbursement submission for using the FlexView system to treat atrial fibrillation, even as a stand-alone procedure, cannot be medically necessary or reasonable and necessary because it is not specifically approved for that purpose."); *Bennett I*, 747 F. Supp. 2d at 778 (determining that the relator failed to allege any false statement in the off-label promotion because the relators did not allege that the defendant hid the off-label nature of the use, "[n]or d[id] the relators allege specific false statements by Medtronic that the Cardioblate system is a first-line treatment for atrial fibrillation," rendering it "medically necessary"). Instead,

Nowak's claim is more similar to that in *Franklin*, where the court cited "eleven specific examples of fraudulent statements which medical liaisons . . . were trained to give to physicians, and did give to physicians, to induce the purchase of [the drug] for off-label uses." 147 F. Supp. 2d at 48–49 (referring to allegations of false data, false leads from clinical trials, supporting effectiveness for off-label uses, promotional materials saying drug was effective for off-label uses).

Reading the Consolidated Complaint in the light most favorable to Nowak, it appears that although Medtronic took measures to appear not to be presenting its biliary stents as either approved or as safe and effective,[22] Nowak has alleged sufficient facts to infer that both before and after the 2007 changes to its promotional activities, Medtronic also falsely represented its biliary stents as effective means of treating vascular disease.

ii. Medical Devices vs. Drugs

The second challenge that Nowak's FCA fraud claim encounters is the added burden imposed on relators alleging an FCA action based on off-label promotion of *medical devices*, as opposed to

[22]A determination of whether a particular off-label use of a medical device is safe, effective, or "medically necessary" is, in any event, best left to the summary judgment stage of proceedings. *See Carpenter*, 723 F. Supp. 2d at 410 (concluding that whether a drug is recognized in the literature as effective for off-label use is a question more properly addressed at summary judgment).

off-label promotion of pharmaceuticals. *See Bennett I*, 747 F. Supp. 2d at 777 ("The cases recognize that off-label use of a drug or medical device is distinct from a medically unnecessary use of that drug or device." (citations omitted)). Off-label promotion cases involving medical devices are uniquely complicated by the relatively more permissive and undefined nature of Medicare and Medicaid coverage of "off-label" medical devices: "While Medicare and Medicaid typically do not reimburse off-label prescriptions for drugs, . . . eligibility for reimbursement [of Category B medical devices] depends on whether the procedure performed is 'medically necessary' or 'reasonable and necessary.'" *Id.* at 754; *see also Svidler*, 2004 WL 2005781, at *7 (discussing 42 C.F.R. § 411.15(o)).

Thus, while in off-label drug promotion cases it may be sufficient to allege that the defendant "induced and seduced [health care providers] into prescribing [a drug] for off-label uses to their patients, including federally insured patients," *Duxbury*, 579 F.3d at 29, such an allegation without reference to the device's safety and efficacy will be insufficient when alleging off-label promotion of a Category B medical device.

As Class II devices, Medtronic's biliary stents appear to constitute Category B investigational devices that may be reimbursable when used in an off-label use if "medically

necessary" or "reasonable and necessary."[23] *See supra* Part I.C. Thus, to the extent that Nowak's claim alleges that the claims for off-label use are "categorically" false because the device is unapproved for that use (and thus "misbranded" or "adulterated" or "investigational"), she fails adequately to state a claim for relief in accordance with Rule 12(b)(6). *Compare Bennett II*, 2011 WL 1231577, at *26 ("For medical devices . . ., the relator must allege sufficient facts to support an inference that the use of the device is not 'medically necessary' or 'reasonable and necessary' under Medicare regulations."), *with Strom ex rel. United States v. Scios, Inc.*, 676 F. Supp. 2d 884, 891 (N.D. Cal. 2009) (denying motion to dismiss in off-label promotion case in which "the government allege[d] that Defendants' marketing activities created the market for the outpatient use of Natrecor, and that Defendants encouraged such a use even though they had no credible evidence that Natrecor was effective in that context," and that "the drug was not, in fact, effective when used for the

[23]DHHS regulations state that Medicare coverage excludes "[e]xperimental or investigational devices, except for certain devices," including Category B non-experimental/investigational devices. 42 C.F.R. § 411.15(o). A Category B device is "a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type." 42 C.F.R. § 405.201(b).

off-label purpose" and so nonreimbursable under 42 U.S.C. § 1395y).

Nowak relies almost entirely upon the flawed rationale that because the biliary stents are unapproved for use in the biliary tree, they are "categorically" or "statutorily" nonreimbursable under the various federal health care programs. (*See* Consol. Compl. ¶¶ 8–9, 140; Pls.' Opp. at 8–9, 27, 29.) However, as the text of that regulation makes clear, certain investigational devices (such as Class II biliary stents) may be reimbursable. *See* 42 C.F.R. § 411.15(o); *Bennett II*, 2011 WL 1231577, at *26–27 ("Alleging that the use of the FlexView system to treat atrial fibrillation is 'experimental' does not allege a basis for an inference that such use of the system is categorically medically unnecessary.").

Nowak augmented her initial argument, following the hearing on this motion, by arguing in briefing that the use of biliary stents in the vasculature is neither "safe" nor "effective." Fortunately for Nowak, the Consolidated Complaint alleges facts sufficient to support this allegation. Indeed, the Consolidated Complaint alleges sufficient facts to infer not only that the use of biliary stents in the vasculature is not "medically necessary," safe, or effective, but also that Medtronic was aware of the stents' deficiencies.[24]

[24]The Consolidated Complaint alleges: (1) the FDA expressed concerns regarding the safety of off-label use of biliary stents

Consequently, for purposes of this motion to dismiss, I am satisfied that Nowak has pled sufficient facts to suggest that Medtronic falsely presented its biliary stents to health care providers as effective for use in the vasculature despite knowing both that the devices were not approved for such a use because they may not be safe and effective for such a use. Unlike in *Bennett I* and *Bennett II*, in which the relator alleged only that the devices were not medically necessary because they were unapproved, *see, e.g.*, *Bennett II*, 2011 WL 1231577, at *27 ("The authorities cited by the relator do not provide a basis to infer that a reimbursement submission for using the FlexView system to treat atrial fibrillation, even as a stand-alone procedure, cannot be medically necessary or reasonable and necessary because it is not specifically approved for that purpose."), Nowak

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as early as 1999 (Consol. Compl. ¶¶ 37–38); (2) Medtronic's Assurant stent was recalled in 2003 due to reported adverse events in off-label use (Consol. Compl. ¶ 126); (3) during development of the Racer stent, relator Dodd told Medtronic about concerns that the Racer would crack when used in the pulsating vascular veins (Consol. Compl. ¶ 66); (4) a vascular physician attending a Medtronic Clinical Advisory Board in 2006 told relator Dodd that Medtronic needed to legitimize the biliary stents and get pre-market approval for vascular use (Consol. Compl. ¶ 91); (5) the FDA informed Medtronic and other manufacturers that it had seen an increase in adverse events due to off-label use of biliary stents (Consol. Compl. ¶ 129); (6) Medtronic informed its customers that the devices were not cleared as safe for use in the vasculature (Consol. Compl. ¶¶ 129, 132); and (7) a 2008 *American Journal of Therapeutics* article detailed the dangers and high rate of malfunctions of biliary stents used in the vasculature (Consol. Compl. ¶¶ 137–40).

adequately alleges that Medtronic's biliary stents were not "medically necessary."

d. Scienter

In order for her § 3729(a)(1) claim to succeed, Nowak must demonstrate that Medtronic knew that healthcare providers would submit false claims for reimbursement as a "natural, ordinary, and reasonable consequence of its" off-label promotion scheme. *Allison Engine, Co.*, 553 U.S. at 672–73; *Lisitza*, 765 F. Supp. 2d at 124. Given that ninety percent of biliary stents were used for unapproved purposes, that the majority of those with vascular diseases requiring stenting are older individuals, and that eighty percent of all medical devices are paid for through Medicare and Medicaid, it is entirely foreseeable that the health care providers who relied on Medtronic's allegedly false assertions that the stents were safe and effective for use in the vasculature would submit reimbursements to the government for those stents. *See, e.g.*, *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1326 (11th Cir. 2009) ("We will assume *arguendo* that when a physician writes an off-label prescription with knowledge or intent that the cost of filling that prescription will be borne by the federal government, and when a claim is ultimately submitted to the federal government to pay for that prescription, 31 U.S.C. § 3729(a)(1) may have been violated." (citing *Rost*, 507 F.3d at 732–33)); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 n.31 (5th Cir. 2009) ("The doctor can cause the

fraud by putting a fraudulent record into a system that he knows will ministerially crank out a fraudulent bill to the Government. Describing such a system serves the same purpose as naming the individual who hit the submit button.").

The specific intent to defraud required for a pre-FERA § 3729(a)(2) claim carries a heavier burden of demonstrating a causal link. In at least one circuit, an allegation that the defendant intended to induce physicians to write off-label prescriptions was held insufficient to plead the causal link between the false statement and the government's decision to pay: "We cannot infer that because [the defendant] allegedly intended its marketing campaign to convince physicians to write off-label prescriptions, [the defendant] intended for that campaign to influence the government's decision to pay for those prescriptions." *See Hopper*, 588 F.3d at 1330; *see also Amgen Inc.*, 2011 WL 2937420, at *6 (stating that the plaintiff–states "must show that the defendants knowingly caused the submission of the false or fraudulent claims, the submission of false records or statements to get the false or fraudulent claims paid, or otherwise conspired to defraud the state by getting the false or fraudulent claims paid"). In doing so, the Eleventh Circuit distinguished the First Circuit's decision in *Duxbury*, where the defendant had provided physicians with free samples with the specific purpose that the physicians would then submit reimbursement claims for those drugs. *Id.*

Were I to apply *Hopper*'s reasoning, I might find Nowak fails to allege this specific intent element of the causal link. She alleges sufficient facts to suggest that false submissions — assuming that the off-label use was not "medically necessary" — resulted from their off-label promotion to health care providers. However, she does not allege that Medtronic intended that its customers then submit reimbursement claims to the government. However, "much knowledge is inferential," *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009), and applying *Duxbury*, as I must, I am satisfied that the Consolidated Complaint alleges sufficient facts to infer that Medtronic intended that the physicians would consider its biliary stents as safe and effective therapy for vascular disease and would use the stents in routine vascular stenting procedures that would, in turn, form the basis of reimbursement claims to the government. Furthermore, under the more liberal "knowing" standard applicable to the post-FERA version of § 3729(a)(2), § 3729(a)(1)(B), Nowak's pleadings would be sufficient. *See* 31 U.S.C. § 3729(b)(1)(A)(iii) (stating that one definition of "knowing" and "knowingly" is "acts in reckless disregard for the truth or falsity of the information").

e. Materiality

Under § 3729(a)(2), a plaintiff must also prove that the defendant intended that the false record or statement be material to the Government's decision to pay or approve the false claim.

Allison Engine Co., 553 U.S. at 665. A statement is material "if it has 'a natural tendency to influence, or [is] capable of influencing, the decision of the decisionmaking body to which it was addressed.'" *Hutcheson*, 2011 WL 2150191, at *15 (quoting *United States ex rel. Loughren v. Unum Grp.*, 613 F.3d 300, 307 (1st Cir. 2010)). "'Express contractual language may 'constitute dispositive evidence of materiality,' but materiality may be established in other ways, 'such as through testimony demonstrating that both parties to the contract understood that payment was conditional on compliance with the requirement at issue.'" *Id.* at *15 (quoting *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1269 (D.C. Cir. 2010)). However, "[i]f a . . . defendant makes a false statement to a private entity and does not intend the Government to rely on that false statement as a condition of payment, the statement is not made with the purpose of inducing payment of a false claim 'by the Government.'" *Allison Engine Co.*, 553 U.S. at 671–72. Such a claim fails because "the direct link between the false statement and the Government's decision to pay or approve a false claim is too attenuated to establish liability." *Id.*

Courts have, nevertheless, declined to grant motions to dismiss when the relator fails explicitly to allege a nexus between the off-label promotion and the claims for reimbursement: "When at the initial pleading stage a relator has made specific allegations of an of-label marketing scheme that includes

kickbacks and claims for reimbursement, but is unable to link them seamlessly together, a rigid showing of causation is not a [required] ticket to discovery." *Carpenter*, 723 F. Supp. 2d at 405 (citing *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 17 (D. Mass. 2008) (concluding that a showing of causation "is a challenge more appropriate for summary judgment")); *United States v. Carell*, — F. Supp. 2d —, 2011 WL 1060669, at *6 (M.D. Tenn. Mar. 21, 2011) (concluding that "whether the Government relied, in some fashion, on Defendants' submission in making payments is not something which can be readily discerned merely from the pleadings" and is best "considered after the proof is developed"). Such a "rigid showing" is particularly inappropriate where, as here, the relator does not have pre-discovery access to the information that could demonstrate causation. *Carpenter*, 723 F. Supp. 2d at 405.

Moreover, in *Hutcheson*, the First Circuit rejected "Blackstone's argument that Medicare would excuse these violations because of a bureaucratic mechanism or because of an implicit medical necessity requirement [on the grounds that doing so] impermissibly cabins what the government may consider material." 2011 WL 2150191, at *15. All that is required at the motion to dismiss stage is "that the [misrepresentations] were capable of influencing Medicare's decision as to whether to pay

the hospital and physician claims." *Id.* This initial hurdle has been met.

f. Conclusion

For the foregoing reasons, I am satisfied that Nowak has alleged sufficient facts to state claims for which relief can be granted under both provisions of the FCA because Medtronic's scheme allegedly sought submission of claims not properly reimbursable by the government. However, her claims rely heavily on inferences and statistical extrapolations that, while sufficient to satisfy Rule 12(b)(6), may not be considered sufficient to satisfy the pleading requirements of Rule 9(b). I turn now to those requirements.

C. Rule 9(b)

FCA allegations and their state counterparts are subject to the heightened pleading standards of Federal Rule of Civil Procedure 9(b).[25] *Rost*, 507 F.3d at 731. Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). According to this standard, "a complaint must specify the time, place, and content of an alleged false representation." *Rost*, 507 F.3d at 731 (citation and internal

[25]The requirements of Rule 9(b) "generally appl[y] to state law fraud claims brought in federal court," and my determinations with respect to Nowak's FCA claims apply also to her claims under the anti-fraud statutes of the states and the District of Columbia. *See United States ex rel. Rost v. Pfizer*, 507 F.3d 720, 731 n.8 (1st Cir. 2007).

quotation marks omitted). However, while "[c]onclusory allegations . . . are not sufficient to satisfy Rule 9(b)[,] . . . [t]he rule may be satisfied . . . where, although some questions remain unanswered, the complaint as a whole is sufficiently particular to pass muster under the FCA." *Gagne*, 565 F.3d at 45 (citations and quotation marks omitted); *see also Franklin*, 147 F. Supp. 2d at 46–47 (observing that, reading Rule 9(b) in conjunction with Federal Rule of Civil Procedure 8(a), "while Relator must allege the circumstances of the fraud, he is not required to plead all of the evidence or facts supporting it" (citation omitted)). Additionally, the First Circuit has acknowledged that "where facts underlying the fraud are 'peculiarly within the defendant's control,' a plaintiff may be excused from pleading the circumstances of the fraud with a high degree of precision." *Franklin*, 147 F. Supp. 2d at 47 (quoting *Boston & Me. Corp. v. Hampton*, 987 F.2d 855, 866 (1st Cir. 1993)).[26]

The First Circuit has recognized, with respect to the requirements of Rule 9(b) particularity, "a distinction between a *qui tam* action alleging that the defendant made false claims to

[26]Neither of the First Circuit's recent FCA opinions addressed the question of compliance with Rule 9(b). *See Amgen Inc.*, 2011 WL 2937420, at *6 n.8 (declining to address the defendants' Rule 9(b) arguments because the district court had yet to consider the issue); *Hutcheson*, 2011 WL 2150191, at *6 n.8 (same).

the government, and a *qui tam* action in which the defendant induced *third parties* to file false claims with the government." *Duxbury*, 579 F.3d at 29 (emphasis in original). The latter is afforded more leniency in pleading than the former. *Id.* In the claims that survive the jurisdictional bars, Nowak alleges both direct and induced indirect false claims. She alleges that Medtronic promoted and sold biliary stents directly to federal health care programs such as TRICARE/CHAMPUS and CHAMPVA for unapproved and unsafe off-label use in the vasculature. (Consol. Compl. ¶¶ 8, 51.) She also alleges that, through its off-label promotion scheme, Medtronic induced others to submit claims for reimbursement to the government for nonreimbursable off-label use of biliary stents in the vasculature. (Consol. Compl. ¶ 9.)

1. Direct Claims

Nowak's claims alleging fraudulent direct sales to a government agency must be dismissed. Following the First Circuit's decision in *Karvelas*, judges of this court have held that, "[i]n cases where the defendant directly presents the claim to the government, the plaintiff must provide details identifying particular false claims submitted, including who filed the claims, the content of the claims, when such claims were submitted, where such claims were submitted, and how much it sought in payment." *United States ex rel. Westmoreland v. Amgen,*

Inc., 738 F. Supp. 2d 267, 275 (D. Mass. 2010)[27] (citing *Karvelas*, 360 F.3d at 225); *see also United States ex rel. Crennen v. Dell Mktg. L.P.*, 711 F. Supp. 2d 157, 161 (D. Mass. 2010).

Nowak claims that Medtronic violated the FCA by directly selling biliary stents to government-run facilities for off-label uses. Sales to certain government agencies, such as the VA, were conclusorily referenced in the Consolidated Complaint, but not tied to any particular reimbursement claim or device sale. (*See* Consol. Compl. ¶ 8.) Additionally, in a footnote in briefing her opposition to the Motion to Dismiss, Nowak provides examples of allegedly off-label sales of particular stents by two sales representatives to VA-run hospitals on specific dates and

[27]The opinion cited in the text was issued in the same litigation that generated the First Circuit's decision last week in *Amgen Inc.*, affirming in part and reversing in part a prior decision on defendants' first motions to dismiss. 2011 WL 2937420, at *11. In his first published opinion on the matter, *United States ex rel. Westmoreland v. Amgen, Inc.*, 707 F. Supp. 2d 123 (D. Mass. 2010), Judge Young dismissed the relator's Third Amended Complaint, the intervening states' First Amended Complaint, and all claims against various of Amgen's co-defendants. The relator and the states appealed the dismissal of the state claims to the First Circuit. Meanwhile, following the relator's motion to reconsider and motion to amend her complaint, Judge Young amended his first order to dismiss the relator's claims to provide that the decision was without prejudice. *See United States ex rel. Westmoreland v. Amgen, Inc.*, 738 F. Supp. 2d 267, 270 & n.1 (D. Mass. 2010). The relator thereafter filed a Fourth Amended Complaint with respect to the federal FCA claims, which survived the subsequent motion to dismiss in the opinion cited in the text. *Id.* at 280–81; *see also Amgen Inc.*, 2011 WL 2937420, at *2 & n.2.

suggests that similar sales were made to VA hospitals in other cities. (Opp. at 36 n.137.)

Nowak's direct sales claim is similar to the unsuccessful claim made by the relator in *Franklin*. The *Franklin* court dismissed a claim involving direct sales to VA because "allegations do not specify which [of defendant's] personnel engaged in this conduct, where such conduct took place, which VA personnel were involved, or any specific fraudulent statements made to personnel at the Veterans Administration." 147 F. Supp. 2d at 49–50.

Accordingly, Nowak's largely conclusory allegations regarding direct sales to government agencies later purportedly reimbursed by CHAMPVA or TRICARE/CHAMPUS do not meet the requirements of Rule 9(b) and must be dismissed.

2. Indirect Claims

With respect to third-party submissions of false claims, Medtronic again alleges that Nowak fails to meet her pleading burden under Rule 9(b) because she does not list any specific requests for reimbursement or specific false statements made by Medtronic in furtherance of obtaining any reimbursements. Nowak counters that she need not provide specific claims for reimbursement in the case of indirect, third-party claims and that she outlined the fraudulent scheme in sufficient detail to give Medtronic notice of the case against it.

When a relator alleges that the defendant caused another to submit a false claim, the First Circuit has "held that a relator could satisfy Rule 9(b) by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to each false claim." *Duxbury*, 579 F.3d at 29 (quoting *Rost*, 507 F.3d at 733). That Nowak fails to provide "the time, place, and content of an[y] alleged false representation" is thus *per se* fatal.[28] *See Gagne*, 565 F.3d at 45.

Two recent First Circuit cases inform my analysis.[29] Both

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[28]In the response to the motion to dismiss, Nowak again points to two specific examples of off-label sales from sales reports, including one dozen stents sold to a vascular specialist. These recorded sales, and allusions to other listings of allegedly off-label sales, demonstrate at least a likelihood that Medtronic engaged in unlawful off-label promotion. However, Nowak fails to provide any evidence that the entities that purchased the biliary stents – supposedly for off-label use – used those stents in a manner not "medically necessary" and then sought reimbursement for those purchases from the government.

[29]Some courts have taken a more lenient approach to Rule 9(b) in the FCA context than has the First Circuit in *Rost* and *Duxbury*. This is particularly true in the context of off-label promotion claims, for which evidence of the numerous claims involved in a nationwide off-label promotion scheme could be considered "ungainly and unfair." *Strom ex rel. United States v. Scios, Inc.*, 676 F. Supp. 2d 884, 894 (N.D. Cal. 2009). For example, the *Strom* court found that because "[t]he gravamen of this action concerns fraudulent inducement of doctors, and the Complaint provides exhaustive allegations relating to this fraud," albeit no details of fraudulent claims submitted, the action could go forward. *Id.* (noting also that the allegations "put defendants on sufficient notice of the nature of the action"). However, the *Strom* court recognized that its approach was more lenient than the First Circuit's. *Id.* at 893 & n.3 (recognizing that the First Circuit "requires the details of the

Rost and *Duxbury* involved allegations that "false claims were allegedly submitted by doctors who were allegedly induced and seduced by defendants[, in this case through kickbacks,] into prescribing [a drug] for off-label uses to their patients, including federally insured patients." *Rost*, 507 F.3d at 732; *Duxbury*, 579 F.3d at 29 (quoting same and noting the similarity of the allegations). The *Rost* court found that the complaint "amply describe[d] illegal practices in which [the defendant] allegedly engaged" but "d[id] not sufficiently establish that false claims were submitted for government payment in a way that satisfies the particularity requirement." 507 F.3d at 732–33. The *Rost* court surmised that it was possible that the doctors who prescribed the drug off-label did not then seek federal reimbursement. *Id.* at 732.

The *Duxbury* court distinguished *Rost* and concluded that "Duxbury d[id] more than 'suggest fraud was possible.'" 579 F.3d at 29–30 (quoting *Rost*, 507 F.3d at 733). Unlike Rost, Duxbury identified eight hospitals that submitted false claims and,

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claims themselves [to] be pleaded with particularity, even if the fraudulent scheme itself is alleged with great particularity"). Similarly, another court found compliance with Rule 9(b) in an off-label promotion case in which relators "alleged with particularity facts regarding defendants' alleged off-label marketing" — but no specific claims — because such information was unlikely to be "within the relators' reach" and "[g]iven the significant proportion of medical care in this country that is financed by Medicare and Medicaid." *United States ex rel. Kennedy v. Aventis Pharm., Inc.*, 512 F. Supp. 2d 1158, 1167 (N.D. Ill. 2007).

although he did not list specific claims, provided "information as to the dates and amounts of the false claims *filed by these providers with the Medicare program*." *Id.* at 30 (emphasis added). The court acknowledged that it was "a close call" even under a "more flexible standard" of Rule 9(b), but ultimately held that Duxbury satisfied the Rule 9(b) requirement because "he has alleged the submission of false claims across a large cross-section of providers that alleges the 'who, what, where and when of the allegedly false or fraudulent representation'" and "has also alleged facts with respect to the medical providers he identifies that support his claim that [the defendant] *intended* to cause submission of false claims." *Id.* (citation omitted) (emphasis added). The *Duxbury* court permitted the evidence of these eight providers' false claims to "support[beyond possibility] a strong inference that such claims were also filed nationwide." *Id.* at 31.

Unlike the relator in *Duxbury*, Nowak can point to no claims for reimbursement to Medicare, Medicaid, or any other federal health care program. She relies entirely on a statistical probability: if ninety percent of all biliary stents are used off-label, and eighty percent of medical device purchases are paid for by Medicare or Medicaid, then a significant portion of the health care providers who bought Medtronic's biliary stents both used those stents for off-label purposes and improperly submitted requests for reimbursement to federal agencies for that

off-label use. This logic, in light of the extensive and detailed allegations regarding Medtronic's active off-label promotional activities, certainly meets a standard of plausibility — even probability — that at least *one* claim was submitted based on the misrepresentations.

Nowak's reasoning, however, omits out an important step in the analysis in the *medical device* context. The use of the biliary stent off-label must not be "medically necessary" in light of the alleged misrepresentation of the stent's safety and efficacy in the vasculature. Identifying such a claim significantly reduces Nowak's statistical probability and would require an individual claim-by-claim review of medical necessity. The categorical approach appropriate for off-label drug use or AKS violations is inapplicable here. Each individual health care provider's medical judgment is an essential element of Nowak's FCA claim, without which she cannot demonstrate that a *false* or *fraudulent* claim was submitted. *See Bennett I*, 797 F. Supp. 2d at 777 ("The decision on medical necessity is made by individual physicians exercising independent professional judgment based on the knowledge of their particular patients."). Thus, with no specific claim alleged, identifying even one false or fraudulent claim may be akin to finding a needle in a haystack. Consequently, I am not satisfied that Nowak's pleading satisfies the flexible, yet still meaningful, standard of particularity required by *Duxbury* and *Rost*. Nowak simply fails to allege *any*

claim for a "medically unnecessary" use and so fails to allege any fraudulent or false *claim* with particularity.

Nowak points to several cases in which district courts have found Rule 9(b) compliance based upon a detailed alleged scheme of fraud but no — or few — specifically alleged claims. For example, at least one court has suggested that impracticality can relax the requirements of Rule 9(b) when "facts underlying the fraud are peculiarly within the defendants' control" or "the alleged scheme of fraud may involve numerous transactions or transactions that occur over a long period of time, and pleading the specifics with regard to every instance of fraudulent conduct may be impractical."[30] *Franklin*, 147 F. Supp. 2d at 47. The First Circuit has recognized that where the relator alleges specific claims in one state or region, such pleadings can satisfy Rule 9(b) requirements by establishing a nationwide inference of fraud. *Duxbury*, 579 F.3d at 30 ("Although [the relator] does not identify specific claims, he has alleged the

[30]*United States ex rel. Franklin v. Parke-Davis, Division of Warner-Lambert Co.*, 147 F. Supp. 2d 39 (D. Mass. 2001), was decided before *Duxbury* and *Rost*, and, to the extent that it applies a more forgiving pleading standard than the these most recent cases, it is not controlling. In discussing "split authority" regarding Rule 9(b) pleading standards, the *Strom* court recognized that *Franklin* adopted a more permissive approach than *Rost* and *Duxbury* by "focus[ing] on the details of the allegations of fraudulent conduct and the scheme of misrepresentation, rather than on the details of the individual claims" as did *Rost* and *Duxbury*. *Strom*, 676 F. Supp. 2d at 893 n.4. However, the conclusions drawn in *Franklin* with respect to the extrapolation theory are largely consistent with the later First Circuit cases.

submission of false claims across a large *cross-section of providers* that alleges the 'who, what, where, and when of the allegedly false or fraudulent representation.'" (emphasis added)); *Carpenter*, 723 F. Supp. 2d at 409–10 (collecting cases); *see also United States ex rel. Wall v. Vista Hospice Care,* Inc., — F. Supp. 2d —, 2011 WL 816632, at *4 (N.D. Tex. Mar 9, 2011) ("*If combined with sufficient number of specific, verifiable cases*, an analysis extrapolating to other patients is not fatal to [a relator's] complaint, but rather tends to strengthen the inference of fraud." (citing *Duxbury*, 579 F.3d at 29) (emphasis added)). These exceptions are particularly applicable in the off-label promotion context. However, even in cases employing this extrapolation approach, the sucessful relators have identified a nucleus of specific allegedly fraudulent or false claims, or "specific, verifiable cases." *Wall*, 2011 WL 816632, at *4.

For example, in *Franklin*, allegations of off-label promotion and kickbacks were found to comply with Rule 9(b) because they (1) identified the individuals who trained medical liaisons to promote off-label, the medical liaisons who promoted off-label, and the physicians targeted; (2) alleged that the off-label promotion "resulted in the submission of numerous . . . prescriptions that were ineligible for reimbursement under Medicaid because they were prescribed for an off-label use"; (3) were confined to a specific time period; and (4) described a

marketing scheme that used kickbacks and misleading marketing to increase off-label use. *Id.* at 48. Indeed, it appears that in all cases in which a court has found Rule 9(b) satisfied under this extrapolation approach, the relators alleged at least some specific false claims. *See, e.g.*, *Lusby*, 570 F.3d at 854 (finding pleadings sufficient when "[t]he complaint names specific parts shipped on specific dates, and it relates details of payment," but does not produce invoices or shipping paperwork); *Lisitza*, 765 F. Supp. 2d at 129 (finding a claim "sufficiently pled" where it "specifies the relevant time period (1999–2004), the manner in which the kickbacks were paid (through 'rebates,' payments for data, 'grants,' sponsorship fees, and other similar payments, . . . the claims alleged to be false that flowed from the various kickback schemes," and "attached to its complaint the specific contracts at issue, certain 'key' communications . . ., and internal . . . memoranda and email messages containing . . . discussions of the rebate programs" (internal citations to the record omitted)); *Westmoreland*, 738 F. Supp. 2d at 276 (finding pleadings sufficient under Rule 9(b) because more than half of the drug's revenue comes from Medicare or Medicaid reimbursements; that the majority of patients with relevant disease are covered by Medicare or Medicaid; that re-enrollment forms are submitted often; and "the Complaint contains allegations regarding particular medical providers who submitted

legally and factually false claims at the Defendants' encouragement").

By contrast, in those cases in which the relator alleged no representative sample of false claims, courts have found that the relator did not satisfy Rule 9(b), regardless of the persuasiveness of the showing of the unlawful fraudulent scheme or conduct. *See, e.g.*, *Gagne*, 565 F.3d at 47 (dismissing on Rule 9(b) grounds because the relators "d[id] not provide any details about the invoices themselves[, did] not show how the time sheets had a material effect on the government's decision to pay the invoices or any other claim"); *Rost*, 507 F.3d at 733 (finding pleading insufficient where it "raise[d] facts that suggest fraud was possible; but the complaint contained no factual or statistical evidence to strengthen the inference of fraud beyond possibility"); *Wall*, 2011 WL 816632, at *3–4 (finding a statistical inference that Medicaid and Medicare participate in as much as ninety-three percent of related cases insufficient under Rule 9(b) because there was otherwise no "verfiable cases" identifying an alleged false claim); *Bennett I*, 747 F. Supp. 2d at 769 (finding the off-label promotion claim not to have satisfied Rule 9(b) because "the relators have not . . . provided a 'representative sample' or even an 'instance of submission'" of a false claim or "a factual basis to support a belief that a specific physician or hospital submitted a false claim" (citations omitted)).

Even in *Duxbury*, on which Nowak relies heavily, but which the First Circuit deemed a "close call," the relator "identified, as to each of the medical providers (the who), the illegal kickbacks (the what), the rough time periods and locations (the where and when), and the filing of the false claims themselves." 579 F.3d at 30. And, the *Duxbury* court noted, the relator had alleged specific intent with respect to the § 3729(a)(2) claims: "Moreover, as to his (a)(2) claims, Duxbury has also alleged facts with respect to the medical providers he identifies that support his claim that [the defendant] *intended* to cause the submission of false claims." *Id.* (emphasis in original). Nowak has not provided any similar specific allegations.

Although the Nowak allegations are similar to these extrapolation cases, they do not identify "the physicians targeted," but rather allege that *any* purchaser of the biliary stents was a purported target of the fraudulent scheme. Nor does she identify a definite and limited time during which the false claims were filed. Moreover, Nowak fails to allege the submission of *any* claim for a use of Medtronic's biliary stents that was *not* "medically necessary." She thus has not alleged *any* fraudulent or false *claim* with particularity. With no fraudulent or false claim, there is no fraud actionable under the FCA.

Finally, unlike in *Duxbury*, 579 F.3d at 30, Nowak fails to allege the required intent element. Nowak does not allege that Medtronic *intended* the government to pay for the biliary stents

that were not medically necessary. In attempting to surmount this deficiency, Nowak relies upon *Westmoreland*, in which the district court determined that the complaint survived the strictures of Rule 9(b) despite not detailing specific claims because the relator "described a marketing scheme focused on exploiting the profit providers could gain from claiming reimbursement for all overfill [from liquid prescriptions], and has detailed instances where providers have successfully encouraged particular providers to bill for unadministered or unnecessary overfill." 738 F. Supp. 2d at 277. However, there, the allegations included descriptions of particular instances in which the defendant's staff encouraged healthcare providers to submit fraudulent claims for non-reimbursable off-label use. *Id.* Similarly, in *Franklin*, the relator detailed the defendant's efforts "to coach doctors on how to conceal the off-label nature of the prescription." 147 F. Supp. 2d at 46. Nowak alleges no such coaching or encouragement by Medtronic. Medtronic clearly intended to profit from off-label sales, but it is unclear if Medtronic intended to do so specifically at the expense of government coffers tapped to pay non-reimbursable claims.

Thus, even in cases in which relators "need not plead the details of specific false claims," relators must provide more than merely a detailed outline of a fraudulent scheme. *In re Pharm. Indus.,* 538 F. Supp. 2d at 391. "Articulating a theory as

to how a company *could* violate subsection [3729(a)], without more, is insufficient to comply with the requirements of Rule 9(b)." *Crennen*, 711 F. Supp. 2d at 162 (emphasis in original). Nowak's allegations, though particular with respect to the improper off-label *promotion*, fail to allege the *fraud* with the requisite particularity. *See Rost*, 507 F.3d at 733. Accordingly, they must be dismissed.

3. State Claims

In addition to the federal FCA claims that constitute the foundation for her action, Nowak also asserts violations of similar statutes in twenty-one states and the District of Columbia. In order to satisfy Rule 9(b), Nowak must allege some specificity with respect to each asserted state and cannot rely upon generalized pleadings. *Wall*, 2011 WL 816632, at *8 (dismissing without prejudice state FCA claims for those states in which the relator "provide[d] no details of the alleged fraud" because "to plead properly, even where the allegations are stated on information and belief, a plaintiff must set forth in the complaint the facts supporting the belief"). Although one judge in this District has found that specifically pled claims in one state are sufficient to support an inference of a nationwide scheme and the pleadings requirements for all state counts, *see Carpenter*, 723 F. Supp. 2d at 409–10, no such specific claims have been pled here as to *any* state.

As with her federal claims, Nowak fails to identify any specific fraudulent or false claim submitted to any state or the District of Columbia. In each count alleging such violations, she generally alleges that "previously discussed sales reports document with great particularity the scores of customers across the country who have been marketed to and sold biliary stents for off-label, unapproved use." (Consol. Compl. ¶¶ 181, 188, 195, 202, 209, 216, 223, 230, 237, 244, 251, 258, 265, 272, 279, 286, 295, 300, 307, 314, 321, 328.) The sales reports are not attached to the Consolidated Complaint, and, in any case, simply list the salesperson, product, amount, and customer for each sale. (*See* Stevenson Decl., Ex. A.) The sales reports do not indicate whether the sold devices were implanted, used in the vasculature, were not medically necessary, or paid for by private insurance, patients, or state and/or federal programs.[31]

Accordingly, I will dismiss Nowak's state FCA claims.

[31]The Consolidated Complaint itself identifies three apparently illustrative sales: (1) Brad Moulds sold seventy-five biliary stents to the Kansas Heart Hospital (which presumably used them in the vasculature), (2) Danny Lewis sold two biliary stents to a cardiologist for an iliac occlusion on September 21, 2007, and (3) Salvatore Sparacino sold more than one dozen biliary stents to Access, Inc., which is a management company specializing in vascular procedures. (Consol. Compl. ¶¶ 115–16.) Only one of these examples, the sale to Kansas Heart Hospital, identifies the state. However, this allegation is insufficient either to state a claim or to satisfy the particularity pleading requirements.

IV. CONCLUSION

For the reasons set forth more fully above, I GRANT Medtronic's motion to dismiss (08-10368 Dkt. No. 44; 09-11625 Dkt. No. 24.) with respect to the relators' fraud claims (Counts I-XXVIV) but DENY Medtronic's motion to dismiss as to relator Nowak's allegation of retaliation claims (Counts XXV-XXVII).

/s/ Douglas P. Woodlock
DOUGLAS P. WOODLOCK
UNITED STATES DISTRICT JUDGE